Corrections

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This section of the FEDERAL REGISTER contains editorial corrections of previously published Presidential, Rule, Proposed Rule, and Notice documents. These corrections are prepared by the Office of the Federal Register. Agency prepared corrections are issued as signed documents and appear in the appropriate document categories elsewhere in the issue.

COMMITTEE FOR PURCHASE FROM THE BLIND AND OTHER SEVERELY HANIDCAPPED

Procurement List 1990; Additions

Correction

In notice document 90-18159 beginning on page 31620 in the issue of Friday, August 3, 1990, make the following correction:

On page 31620, in the second column, the **COMMENTS** date should read "September 4, 1990."

BILLING CODE 1505-01-D

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Parts 261, 264, 265, 266, 271, and 302

[SWH-FRL-3816-1, EPA/OSW-FR-90-FFF]
RIN 2050-AA78

Hazardous Waste Management System; Identification and Listing of Hazardous Waste; Toxicity Characteristic Revisions

Correction

In rule document 90-18073 beginning on page 31387 in the issue of Thursday, August 2, 1990, make the following corrections:

1. On page 31387, in the third column the docket line was incorrect and should read as set forth above.

2. On the same page, in the third column, under **DATES**, in the last line, "October 31, 1990" should read "November 2, 1990".

3. On page 31388, in the third column, in the note, in the second and third lines, the bracketed phrase should be removed and the date "November 2, 1990" should be inserted.

4. On page 31390, in the third column at the end of the document, the file line was omitted and should read:

[FR Doc. 90-18073 Filed 8-1-90; 8:45am]

BILLING CODE 6560-50-M

BILLING CODE 1505-01-D

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Social Security Administration

20 CFR Part 416

RIN 0960-AC48

Subpart L; Resources and Exclusions; Exclusion From Resources of Funds Set Aside for Burial and Burial Spaces

Correction

In rule document 90-16145 beginning on page 28373 in the issue of Wednesday, July 11, 1990, make the following corrections:

1. On page 28373, in the second column, in the first paragraph of the **SUPPLEMENTARY INFORMATION**, in the third line from the end, "to" should read "for".

2. On page 28374, in the first column, in the eighth line from the top, "10" should read "100".

3. On the same page, in the second column, in the first full paragraph, in the sixth line, "and" should read "through".

BILLING CODE 1505-01-D

DEPARTMENT OF TRANSPORTATION

Coast Guard

33 CFR Parts 175 and 181

[CGD 81-023]

RIN 2115-AA58

Equipment Requirements for Recreational Boats; Personal Flotation Devices

Correction

In rule document 90-17731 beginning on page 32032 in the issue of Monday, August 6, 1990, make the following corrections:

§ 175.17 [Corrected]

1. On page 32034, in the second column, in § 175.17, in the first line of the introductory text, "Type PFD" should read "Type V PFD".

PART 181—MANUFACTURER REQUIREMENTS

2. On the same page, at the bottom of the same column, the heading for part 181 should read as set forth above.

BILLING CODE 1505-01-D

federal register

Friday
August 10, 1990

Part II

Department of Labor

Occupational Safety and Health Administration

29 CFR Part 1910

Occupational Exposure to 1,3-Butadiene; Proposed Rule and Notice of Hearing

DEPARTMENT OF LABOR

Occupational Safety and Health Administration

29 CFR Part 1910

[Docket No. H-041]

RIN: 1218-AA83

Occupational Exposure to 1,3 Butadiene

AGENCY: Occupational Safety and Health Administration (OSHA), Department of Labor.

ACTION: Proposed rule and notice of hearing.

SUMMARY: The Occupational Safety and Health Administration (OSHA) is proposing to amend its existing occupational standard that regulates employee exposure to 1,3-Butadiene (BD). The basis for this action is a determination by the Assistant Secretary, based on animal and human data, that OSHA's current permissible exposure limit (PEL) which permits employees to be exposed to BD in concentrations up to 1,000 parts BD per million parts of air (1,000 ppm) as an eight-hour time-weighted average (TWA) is inadequate for employee health protection. OSHA proposes to reduce the PEL for BD to an 8-hour TWA of 2 ppm and a short term exposure limit (STEL) of 10 ppm for 15 minutes to protect the health of workers exposed to BD. An "action level" of 1 ppm as an 8-hour TWA is included in the proposal as a mechanism for exempting an employer from some administrative burdens, such as employee exposure monitoring and medical surveillance, in instances where the employer can demonstrate that the employee's exposures are consistently at very low levels. In order to achieve this reduced PEL, OSHA proposes a number of requirements including certain provisions for exposure control, such as engineering controls, work practices and personal protective equipment, measurement of employee exposures, training, medical surveillance, hazard communication, regulated areas, emergency procedures and recordkeeping.

This proposed standard would apply to all employment in all industries covered by the Act, namely general industry, construction, and maritime.

DATES: Comments concerning the proposed standard must be postmarked on or before October 19, 1990.

Notices of Intention to Appear at the informal rulemaking hearings must be postmarked more then ten (10) minutes for their presentations at the hearings and parties who plan to submit documentary evidence at the hearing must submit the full text of their testimony and all documentary evidence postmarked no later than October 19, 1990.

All informal public rulemaking hearings will begin at 10 a.m. each day. Two informal public rulemaking hearings are scheduled to begin on the following dates: Washington, DC, December 11, 1990; and New Orleans, Louisiana, January 8, 1991.

ADDRESSES: Comments are to be submitted in quadruplicate to the Docket Officer, Docket No. H-041 Room N-2634, United States Department of Labor, 200 Constitution Avenue, NW., Washington, DC 20210, Telephone (202) 523-7894. Comments limited to 10 pages or less in length also may be transmitted by facsimile to (202) 523-5046 or 8-523-5046 (for FTS), provided the original and 3 copies of the comment are sent to Docket Officer thereafter.

Notices of Intention to Appear at the informal rulemaking hearings and testimonies and documentary evidence to be presented at the hearings are to be sent to Mr. Tom Hall, OSHA Division of Consumer Affairs, Docket No. H-041 Room N-3649, United States Department of Labor, 200 Constitution Avenue, NW., Washington, DC 20210, Telephone: (202) 523-8615.

The locations of the informal public hearings are as follows: The Washington, DC, hearings will be held in the Auditorium, Frances Perkins Building, 200 Constitution Avenue, NW., Washington, DC 20210. The New Orleans, LA hearings will be held in the Le Pavillon Hotel (Denechaud Room), 833 Poydras Street, New Orleans, LA 70140, Telephone no. 504-581-3111.

FOR FURTHER INFORMATION CONTACT: Mr. James F. Foster, OSHA Office of Public Affairs, United States Department of Labor, Room N-3641, 200 Constitution Avenue, NW., Washington, DC 20210, Telephone (202) 523-8151.

Information Collection Requirements: 5 CFR part 1320 sets forth procedures for agencies to follow in obtaining OMB clearance for information collection requirements under the Paperwork Reduction Act of 1980, 44 U.S.C. 3501 et seq. This proposed BD standard requires the employer to allow OSHA access to records. In accordance with the provisions of the Paperwork Reduction Act and the regulations issued pursuant thereto, OSHA certifies that it will submit the information collection requirements for this proposal to OMB for review under section 3504(h) of that Act.

Public reporting burden for this collection of information is estimated to average five minutes per response. Send comments regarding this burden estimate or any other aspect of this collection of information, to the Office of Information Management, Department of Labor, Room N-1301, 200 Constitution Avenue, NW., Washington, DC 20210; and to the Office of Information and Regulatory Affairs, Office of Management and Budget, Washington, DC 20503.

Federalism: This proposed standard has been reviewed in accordance with Executive Order 12612 (52 FR 41685, October 30, 1987), regarding Federalism. This Order requires that agencies, to the extent possible, refrain from limiting State policy options, consult with States before taking any actions that would restrict State policy options, and take such actions only when there is clear constitutional authority and the presence of a problem of national scope. The Order provides for preemption of State law only if there is a clear Congressional intent for the agency to do so. Any such preemption is to be limited to the extent possible.

Section 18 of the Occupational Safety and Health Act (OSH Act) expresses Congress' clear intent to preempt State laws relating to issues with respect to which Federal OSHA has promulgated occupational safety or health standards. Under the OSH Act a State can avoid preemption only if it submits, and obtains Federal approval of, a plan for the development of such standards and their enforcement. Occupational safety and health standards developed by such Plan-States must, among other things be at least as effective in providing safe and healthful employment and places of employment as the Federal standards.

The Federally proposed BD standard is drafted so that employees in every State would be protected by general, performance oriented standards. To the extent that there are State or regional peculiarities caused by the terrain, the climate, or other factors, State with occupational safety and health plans approved under section 18 of the OSH Act would be able to develop their own State standards to deal with any special problems. Moreover, the performance nature of this proposed standard, of and by itself, allows for flexibility by all States and employers to provide as much safety as possible using varying methods consonant with conditions in each State.

In short, there is a clear national problem related to occupational safety and health for employment exposed to BD. While the individual States, if all

acted, might be able collectively to deal with the health and safety problems involved, most have not elected to do so in the seventeen years since the enactment of the OSH Act. States which have elected to participate under section 18 of the OSH Act would not be preempted by this proposed regulation and would be able to deal with special, local conditions within the framework provided by this performance oriented standards while ensuring that their standard are at least as effective as the Federal standard. State comments are invited on this proposal and will be fully considered before a final rule is promulgated.

State Plans: The 25 States with their own OSHA-approved occupational safety and health plans must adopt a comparable standard within six months of the publication date of a final standard. These States include: Alaska, Arizona, California, Connecticut, [for State and local government employees only), Hawaii, Indiana, Iowa, Kentucky, Maryland, Michigan, Minnesota, Nevada, New Mexico, New York, [for State and local government employees only), North Carolina, Oregon, Puerto Rico, South Carolina, Tennessee, Utah, Vermont, Virginia, Virgin Islands, Washington, Wyoming. Until such time as a State standard is promulgated, Federal OSHA will provide interim enforcement assistance, as appropriate.

SUPPLEMENTARY INFORMATION:

I. Table of Contents

The preamble to the proposed standard on occupational exposure to BD discusses events leading to the proposal, physical and chemical properties of BD, manufacture and use of BD, health effects of exposure, degree and significance of the risk presented, an analysis of the technological and economic feasibility, regulatory impact and regulatory flexibility analysis, and the rationale behind the specific provisions set forth in the proposed standard. The discussion follows this outline:

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XII. Environmental Impact
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XV. Proposed Standard and Appendices
Appendix A to § 1910.1051: Substance Safety Data Sheet for 1,3-Butadiene
Appendix B to § 1910.1051: Substance Technical Guidelines for 1,3-Butadiene
Appendix C to § 1910.1051: Medical Surveillance for 1,3-Butadiene
Appendix D to § 1910.1051: Sampling and Analytical Method for 1,3-Butadiene
Appendix E to § 1910.1051: Qualitative and Quantitative Fit Testing Procedures for Respirators

References to the rulemaking record are in the text of the preamble. References are given as "Ex." followed by a number to designate the reference in the docket. For example, "Ex. 1" means exhibit 1 in Docket H–041. This document is a request for information by OSHA and the Environmental Protection Agency that was published in the **Federal Register**, January 5, 1984 (49 FR 844).

II. Pertinent Legal Authority

This proposed standard and issuance of a final standard is authorized by sections 6(b), 8(c), and 8(g)(2) of the Occupational Safety and Health Act of 1970 (the Act), 29 U.S.C. 655(b), 657(c) and 657(g)(2). Section 6(b)(5) governs the issuance of occupational safety and health standards dealing with toxic materials or harmful physical agents. It states:

> The Secretary, in promulgating standards dealing with toxic materials or harmful physical agents under this subsection, shall set the standard which most adequately assures, to the extent feasible, on the basis of the best available evidence, that no employee will suffer material impairment of health or functional capacity even if such employee has regular exposure to the hazard dealt with by such standard for the period of his working life. Development of standards under this subsection shall be based upon research, demonstrations, experiments, and other information as may be appropriate. In addition to the attainment of the highest degree of health and safety protection for the employee, other considerations shall be the latest available scientific data in the field, the feasibility of the standards, and experience gained under this and other health and safety laws. Whenever practicable, the standard promulgated shall be expressed in terms of objective criteria and of the performance desired.

Section 3(8) defines an occupational safety and health standard as "a standard which requires conditions, or the adoption or use of one or more practices, means, methods, operations, or processes, reasonably necessary or appropriate to provide safe or healthful employment and places of employment." The Supreme Court has held under the Act that the Secretary, before issuing any new standard, must determine that it is reasonably necessary and appropriate to remedy a significant risk of material health impairment, *Industrial Union Department* v. *American Petroleum Institute*, 488 U.S. 607 (1980). The Court stated that "* * * before he can promulgate any permanent health or safety standard, the Secretary is required to make a threshold finding that a place of employment is unsafe—in the sense that significant risks are present and can be eliminated or lessened by a change in practices" (488 U.S. at 642). The Court also stated "that the Act does limit the Secretary's power to require the elimination of significant risks" (488 U.S. at 644, n. 49).

The Court indicated however, that the significant risk determination is "not a mathematical straitjacket." The Court stated that "OSHA is not required to support its finding that a significant risk exists with anything approaching scientific certainty." The Court ruled that "a reviewing court (is) to give OSHA some leeway where its findings must be made on the frontiers of scientific knowledge," (and that) "the Agency is free to use conservative assumptions in interpreting the data with respect to carcinogens, risking

error on the side of overprotection rather than underprotection" (488 U.S. at 655, 656). The Court also stated that "while the Agency must support its finding that a certain level of risk exists with substantial evidence, we recognize that its determination that a particular level of risk is 'significant' will be based largely on policy considerations". (488 U.S. at 655, 656 n. 62).

After OSHA has determined that a significant risk exists and that such a risk can be reduced or eliminated by the proposed standard, it must set a standard "* * * which most adequately assures, to the extent feasible on the basis of the best available evidence, that no employees will suffer material impairment of health* * *" Section 6(b)(5) of the Act. The Supreme Court has interpreted this section to mean that OSHA must enact the most protective standard possible to eliminate a significant risk of material health impairment, subject to the constraints of technological and economic feasibility, *American Textile Manufacturers Institute. Inc.* v. *Donovan.* 452 U.S. 490 (1981). The Court held that "cost-benefit analysis is not required by the statute because feasibility analysis is" (452 U.S. at 509). The Court stated that the Agency could use cost effectiveness analysis and choose the least costly of two equally effective standards (452 U.S., 531, n. 32).

Section 8(c)(3) gives the Secretary authority to require employers to "maintain accurate records of employee exposures to potentially toxic materials or harmful physical agents which are required to be monitored or measured under section 6." Section 8(g)(2) gives the Secretary authority to "prescribe such rules and regulations as he may deem necessary to carry out [her] responsibilities under this Act."

In addition, the Secretary's responsibilities under the Act are amplified by its enumerated purposes which include:

Encouraging employers and employees in their efforts to reduce the number of occupational safety and health hazards at their places of employment and stimulating employers and employees to institute new and to perfect existing programs for providing safe and healthful working conditions (29 U.S.C. 651(b)(1));

Authorizing the Secretary of Labor to set mandatory occupational safety and health standards applicable to business affecting interstate commerce, and by creating an Occupational Safety and Health Review Commission for carrying out adjudicatory functions under the Act: (29 U.S.C. 651(b)(3));

Building upon advances already made through employer and employee initiative for providing safe and healthful working conditions (29 U.S.C. 651(b)(4));

Providing for the development and promulgation of occupational safety and health standards (29 U.S.C. 652(b)(9)) and providing for appropriate reporting procedures which will help achieve the objectives of this Act and accurately describe the nature of the occupational safety and health problem (29 U.S.C. 651(b)(12)).

Exploring ways to discover latent diseases, establishing causal connections between diseases and work in environmental conditions (29 U.S.C. 651(b)(6));

Encouraging joint labor-management efforts to reduce injuries and diseases arising out of employment (29 U.S.C. 651(b)(13)); and

Developing innovative methods, techniques, and approaches for dealing with occupational safety and health problems (29U.S.C. 651(b)(5)).

Because the BD proposed standard is reasonably related to these statutory goals, and the Agency's judgment is that the evidence satisfies the statutory requirements, and because the proposed standard is feasible and substantially reduces a significant risk of cancer and other adverse health effects, the Secretary preliminarily finds that the proposed standard is necessary and appropriate to carry out her responsibilities under the Act.

III. Events Leading to the Proposed Standard

The present OSHA standard for BD requires employers to assure that employee exposure does not exceed 1,000 ppm determined as an 8-hour TWA (29 CFR 1910.1000, Table Z–1). This standard was adopted by OSHA in 1971 pursuant to section 6(a) of the OSH Act, 29 U.S.C. 655 from an existing Walsh-Healy Federal Standard. The source of this Walsh-Healy Standard was the Threshold Limit Value (TLV) for BD developed in 1968 by the American Conference of Governmental Industrial Hygienists (ACGIH). This TLV was adopted by the ACGIH to prevent irritation and narcosis.

In 1983, the National Toxicology Program (NTP) released the results of an animal study indicating that BD causes cancer in rodents (Ex. 20). Based on the strength of the results of this animal study, ACGIH in 1983 classified BD as an animal carcinogen and in 1984 recommended a new TLV of 10 ppm (Ex. 2–4). Based on the same evidence, on February 9, 1984, the National Institute for Occupational Safety and Health (NIOSH) published a Current Intelligence Bulletin (CIB) recommending that BD be regarded as a potential occupational carcinogen, teratogen and a possible reproductive hazard (Ex. 23–17). On January 5, 1984, OSHA published a Request for Information (RFI) jointly with the Environmental Protection Agency (EPA) (49 FR 844). EPA also announced the initiation of a 180 day review under the authority of section 4(f) of the Toxic Substance Control Act (TSCA) (49 FR 845) to determine "whether to initiate appropriate action to prevent or reduce the risk from the chemical or to find that the risk is not unreasonable". Comments were to be submitted to OSHA by March 5, 1984. On April 4, 1984, OSHA extended the comment period until further notice (49 FR 13389).

Petitions for an Emergency Temporary Standard (ETS) of 1 ppm or less for workers' exposure to BD (Ex. 6–4) were submitted to OSHA on January 23, 1984, by the United Rubber, Cork, Linoleum and Plastic Workers of America (URW), the Oil, Chemical and Atomic Workers (OCAW), the International Chemical Workers Union (ICWU), and the American Federation of Labor and Congress of Industrial Organizations (AFL–CIO). On March 7, 1984, OSHA denied the petitions on the ground that the Agency was still evaluating the health data to determine whether regulatory action was appropriate.

Based on its 180-day review of BD, EPA published on May 15, 1984, an Advance Notice of Proposed Rulemaking (ANPR) (49 FR 20524) to announce the initiation of a regulatory action by the EPA to determine and implement the most effective means of controlling exposures to the chemical BD under the TSCA. EPA was working with OSHA, because available evidence indicates that exposure to BD occurs primarily within the workplace.

Information received in response to this ANPR was used by EPA to develop risk assessments. Subsequently, EPA identified BD as a probable human carcinogen (Group B2) according to EPA's classification of carcinogens, and concluded that current exposures during the manufacturing of BD and its processing into polymers presented an unreasonable risk of injury to human health (Ex. 17–4). Additionally, EPA determined that the risks associated with exposure to BD may be reduced to a sufficient extent by action taken under the OSH Act. Following these findings, EPA, in accordance with section 9(a) of TSCA, on October 10, 1985 (50 FR 41393), referred BD to OSHA to give this Agency an opportunity to regulate the

chemical under the OSH Act. EPA requested that OSHA determine whether the risks described in the EPA report may be prevented or reduced to a sufficient extent by action taken under the OSH Act. EPA requested that if such a determination is made, OSHA issue an order declaring whether the manufacture and use of BD described in the EPA report present the risk therein described. EPA requested OSHA to respond within 180 days, by April 8, 1986 (50 FR 41393).

On December 27, 1985, OSHA published a notice (50 FR 52952) soliciting public comments on EPA's referral report. Based on all the available information, OSHA, on April 11, 1986, responded to the EPA referral report by making a preliminary determination (50 FR 12526) that a revised OSHA standard limiting occupational exposure to BD could prevent or reduce the risk of exposure to a sufficient extent and that such risks had been accurately described by EPA in the report. On October 1, 1986, OSHA published an ANPR (51 FR 35003) to initiate a rulemaking within the meaning of section 9(a) of TSCA. The Agency requested that comments be submitted by December 30, 1986. Twenty-four comments, some of them containing new information, were received in response to the ANPR (Ex. 28–1 to 28–24). Six additional comments were received after the deadline (Ex. 29–1 to 29–6).

OSHA has reviewed the available data and conducted risk assessment, regulatory impact and flexibility analyses. These analyses demonstrate that the proposed standard is technologically and economically feasible and substantially reduces the significant risk of cancers and other adverse health effects such as, but not limited to, reproductive toxicity and anemia.

IV. Chemical Identification, Production and Use

A. Monomer

The chemical 1,3-Butadiene (BD) (Chemical Abstracts Registry Number 106–99–0) is a colorless, noncorrosive, flammable gas with a mild aromatic odor at standard ambient temperature and pressure. It has a chemical formula of C_4H_6, a molecular weight of 54.1, and a boiling point of -4.7 °C at 760 mm Hg, a lower explosive limit of 2%, and an upper explosive limit of 11.5%. Its vapor density is almost twice that of air. It is slightly soluble in water, somewhat soluble in methanol and ethanol, and readily soluble in less polar organic solvents such as hexane, benzene, and toluene (Ex. 17–17). It is highly reactive, dimerizes to 4-vinylcyclohexene, and polymerizes easily. Because of its low odor threshold, high flammability and explosiveness, BD has been handled with extreme care in the industry.

In the United States BD has been produced commercially by three processes: Catalytic dehydrogenation of n-butane and n-butene, oxidative dehydrogenation of n-butene, and recovery from the C_4 co-product (by product) stream from the steam cracking process used to manufacture ethylene, which is the major product of the petrochemical industry. For economic reasons, almost all BD currently made in the U.S. is produced by the ethylene co-product process.

In the steam cracking process for ethylene, a hydrocarbon feedstock is diluted with steam then heated rapidly to a high temperature by passing it through tubes in a furnace. The output stream, containing a broad mixture of hydrocarbons from the pyrolysis reactions in the cracking tubes plus unreacted components of feedstock, is cooled and then processed through a series of distillation and other separation operations in which the various products of the cracking operation are separated for disposal, recycling or recovery.

The cracking process produces from around 0.02 to 0.3 pounds of BD per pound of ethylene, dependent upon the composition of the feedstock. BD is recovered from the C_4 stream by the separation operations. The C_4 stream contains from 30 to 50% BD plus butane, butenes and small fractions of other hydrocarbons. This crude BD stream from the ethylene unit may be refined in a unit on site, or transferred to another location, owned by the same or a different company, to produce purified BD, called monomer plant.

Regardless of the source of the crude BD-ethylene co-product, dehydrogenation, or blending of C_4 streams from other sources, the processes used by different companies to refine BD for subsequent use in polymer production are similar. Extractive distillation is used to effect the basic separation of BD from butanes and butenes and fractional distillation operations are used to accomplish other related separations. A typical monomer plant process is described in the following paragraph.

C_3 and C_4 acetylene derivatives, present in the C_4 co-product stream, are converted to olefins by passing the stream through a hydrogenation reactor. The stream is then fed to an extractive distillation column to separate the BD from butanes and butenes. Several different solvents have been employed for this operation, including n-methylpyrrolidone, dimethylformamide, furfural, acetonitrile, dimethylacetamide, and cuprous ammonium acetate solution. The BD, extracted by the solvent, is stripped from it in the solvent recovery column, then fed to another fractionation column, the methylacetylene column, to have residual acetylene stripped out. The bottom stream from the methylacetylene column, containing the BD, is fed to the BD rerun column, from which the purified BD product is taken off overhead. The solvent, recovered in the solvent recovery column, is recycled to the extractive distillation column with part of it distilled to keep down the level of polymer (Ex. 17–17).

A stabilizer is added to the monomer to inhibit formation of polymer during storage. It is stored as a liquid under pressure, sometimes refrigerated to reduce the pressure, generally in a tank farm in diked spheres. It is shipped to polymer manufacturers and other users by pipeline, barge, tankcar, or tanktruck.

BD is a major commodity product of the petrochemical industry. Total U.S. production of BD in 1987 was 3.0 billion pounds and ranked 35th in chemicals manufactured in the U.S. Although BD is a toxic flammable gas, its simple chemical structure with low molecular weight and high chemical reactivity make it a useful building block for synthesizing other products. In "1,3-Butadiene Use and Substitutes Analysis" (Ex. 17–15), EPA identified 140 major, minor, and potential uses of BD in the chemical industry.

Over 60% of the BD consumed in the United States is used in the manufacture of rubber, about 12% in making adiponitrile which in turn is used to make hexamethylenediamine (HMDA), approximately 8% in making styrene-butadiene copolymer latexes, approximately 7% in producing polychloroprene, and about 6% in producing acrylonitrile-butadiene-styrene (ABS) resins. Lesser amounts are consumed in the production of rocket propellants, specialty copolymer resins and latexes for paint, coating and adhesive applications, and hydrogenated butadiene-styrene polymers used as lubricating oil additives. Some nonpolymer applications include the manufacture of the agricultural fungicides, Captan and Captofol, the industrial solvent sulfolane, and anthroquinone dyes.

B. Polymer

BD based synthetic elastomers are manufactured by polymerizing BD by

itself, by polymerizing BD with other monomers to produce copolymers, and by producing mixtures of these polymers. The largest-volume product is the copolymer of styrene and BD, followed in volume by polybutadiene, polychloroprene, and nitrile rubber. Polybutadiene is the polymer of BD monomer by itself. Polychloroprene is made by polymerizing chloroprene, produced by chlorination of BD. Nitrile rubbers are copolymers of acrylonitrile and BD.

Four general types of processes are used in polymerizing BD and its copolymers: Emulsion, suspension, solution and bulk polymerization. In emulsion and suspension polymerization, the monomers and the many chemicals used to control the reaction are finely dispersed or dissolved in water. In solution polymerization, the monomers are dissolved in an organic solvent such as hexane, pentane, toluene and others. In bulk polymerization, the monomer itself serves as solvent for the polymer. The polymer product, from which end-use products are manufactured, is produced in the form of polymer crumb (solid particles), latex (a milky suspension in water), or cement (a solution).

Emulsion polymerization is the principal process used to make synthetic rubber. A process for the manufacture of styrene-butadiene crumb is typical of emulsion processes. Styrene and BD are piped to the process area from the storage area. The BD is passed through a caustic soda scrubber to remove the inhibitors which were added to prevent premature polymerization. The fresh BD monomer streams are mixed with styrene, aqueous emulsifying agents, activator, catalyst, and modifier, and then fed to the first of a train of reactors. The reaction proceeds stepwise in the series of reactors to around 60% conversion of monomer to polymer. In the cold process, the reactants are chilled and the reactor temperature is maintained at 4 °C to 7 °C (40 °F to 45 °F) and pressure at 0 to 15 psig; in the hot rubber process, temperature and pressure are around 50 °C (122 °F) and 40 to 60 psig, respectively.

The latex from the reactor train is flashed to evaporate unreacted BD which is compressed, condensed and recycled. Uncondensed vapors are absorbed in a kerosene absorber before venting and the absorbed BD is steam stripped or recovered from the kerosene by some other operation. The latex stream is passed through a steam stripper, operated under vacuum, to remove and recover unreacted styrene. The styrene and water in the condensate are separated by decanting. The styrene phase is recycled to the process. Noncondensibles from the stripping column contain some BD and are directed through the BD recovery operations.

Stripped latex, to which an antioxidant has been added, is pumped to coagulation vessels where dilute sulfuric acid and sodium chloride solution are added. The acid and brine mixture breaks the emulsion, releasing the polymer in the form of crumb. Sometimes carbon black and oil are added during the coagulation step since a more intimate dispersion is obtained than by mixing later on.

The crumb and water slurry from the coagulation operation is screened to separate the crumb. The wet crumb is pressed in rotary presses to squeeze out most of the entrained water then dried with hot air on continuous dry belt dryers. The dried product is baled and weighed for shipment.

Production of styrene-butadiene latex by the emulsion polymerization process is similar to that for crumb but is usually carried out on a smaller scale with fewer reactors. For some but not all products, the reaction is run to near completion, monomer removal is simpler and recovery may not be practiced.

Polybutadiene rubber is usually produced by solution polymerization. Inhibitor is removed from the monomer by caustic scrubbing. Both monomer and solvent are dried by fractional distillation, mixed in the desired ratio and dried in a dessicant column. Polymerization is conducted in a series of reactors using initiators and catalysts and is terminated with a shortstop solution. The solution, called rubber cement, is pumped to storage tanks for blending. Crumb is precipitated by pumping the solution into hot water under violent agitation. Solvent and monomer are recovered by stripping and distillation similar to those previously described. The crumb is screened, de-watered, dried and baled.

Polychloroprene (neoprene) elastomers are manufactured by polymerizing chloroprene in an emulsion polymerization process similar to that used for making styrene-butadiene rubber. The monomer, chloroprene (2-chloro-BD), is made by chlorination of BD to make 3,4-dichlorobutene, and dehydrochlorination of the latter to produce polychloroprene.

Nitrile rubbers, copolymers of acrylonitrile and BD, are produced by emulsion polymerization similar to that used to make styrene-butadiene rubber (SBR).

Substantial amounts of BD are used in the production of two other large volume polymers: Nylon resins and ABS resin. DuPont manufactures adiponitrile from BD and uses the product to make hexamethylenediamine which is polymerized in making Nylon resins and fibers, including Nylon 6,6. Acrylonitrile, BD and styrene are the monomers used to make ABS resin which is a major thermoplastic resin. Chemically complex emulsion, suspension and bulk polymerization processes are used by different producers to make ABS polymer. Excess acrylonitrile and styrene monomers are generally disposed of rather than recovered with the exception of BD recovery in some cases.

V. Health Effects

A. Introduction

Until the recent rodent studies conducted by the National toxicology Program (NTP) and by Hazelton Laboratories England for the International Institute of Synthetic Rubber Producers (IISRP), little was known about the recently discovered adverse effects potentially associated with chronic exposure to BD. Health-based standards recommendations were based on prevention of irritation and narcosis.

The rodent studies now indicate that BD is an animal carcinogen, and complementary studies of metabolic products and genotoxicity support the bioassay findings. There is also new evidence that BD may affect the germ cell as well as the somatic cell, raising concerns regarding reproductive and developmental toxicity. Finally, some expidemiologic studies of workers exposed to BD in the synthetic rubber industry show an excess cancer mortality from leukemia/lymphoma, raising further concerns about BD as a potential occupational carcinogen.

B. Carcinogenicity

1. Animal Studies

(i) The NTP Mouse Study. An inhalation bioassay of BD was conducted for the National Toxicology Program (NTP) of the U.S. Department of Health and Human Services by Battelle Pacific Northwest Laboratories (Ex. 23–1). The exposure groups consisted of fifty male and fifty female B6C3F$_1$ mice. The animals were exposed for six hours per day, five days per week to nominal concentrations of 0, 625, and 1250 ppm of BD. Actual concentrations averaged 627 and 1236 ppm for the exposed groups over the course of the experiment. Attempts were made to

limit the animals' exposure to the dimer 4-vinyl-1-cyclohexene. Only three cylinders of BD used during the course of the study had dimer concentrations greater than 100 ppm, and these were used only because no substitutes were available.

The study was originally designed to run for 104 weeks but was terminated at week 60 for the males and week 61 for the females because of high mortality from malignant tumors in the exposed mice. Survival among exposed mice was significantly reduced compared to controls (males: $p<.001$; females: $p<.002$). Among males, survival at termination of the study was 98% for controls, 22% for the low dose group, and 14% for the high dose group. Among females, survival at termination of the study was 92% for controls, 28% for the low dose group, and 60% for the high dose group.

A complete necropsy and histopathological exam was conducted on all animals, including those found dead, unless the animal tissue was excessively autolyzed or cannibalized. Elevated tumor incidence was observed in exposed mice at multiple sites. Table 1 contains a summary of the incidence of primary tumors which occurred at a statistically significantly elevated rate in either of the exposed groups. For the tumor sites presented in Table 1, all incidences except papilloma or carcinoma incidence in the forestomach of male mice showed a significant dose-related trend. Overall tumor incidence among male mice was 20% in the controls, 88% in the low dose group and 80% in the high dose group and among females was 12% in the controls, 82% in the low dose group, and 94% in the high dose group.

TABLE 1.—SUMMARY INCIDENCE OF PRIMARY TUMORS IN B6C3F$_{1a}$ MICE INDUCED BY INHALATION OF 1,3-BUTADIENE

	Controls	625 ppm	1250 ppm
Males:			
Lung: Alveolar/Bronchiolar	2/50(4%)	14/49(29%)	15/49(31%)
Adenoma or Carcinoma	p<.001[b]	p<.001[c]	p<.001[c]
Hematopoietic System	0/50(0%)	23/50(46%)	29/50(58%)
Malignant Lymphoma	p<.001	p<.001	p<.001
Heart: Hemangiosarcoma	0/50(0%)	16/49(33%)	7/49(14%)
	p=.032	p<.001	p=.006
Forestomach	0/49(0%)	7/40(18%)	1/44(2%)
Papilloma or Carcinoma	p=.363	p=.003	p=.473
Females:			
Lung: Alveolar/Bronchiolar	3/49(6%)	12/48(25%)	23/49(47%)
Adenoma or Carcinoma	p<.001	p=.01	p<.001
Hematopoietic System	1/50(2%)	10/49(20%)	10/49(20%)
Malignant Lymphoma	p=.006	p=.003	p=.003
Heart: Hemangiosarcoma	0/50(0%)	11/48(23%)	18/49(37%)
	p<.001	p<.001	p<.001
Liver: Hepatocellular	0/50(0%)	2/47(4%)	5/49(10%)
Adenoma or Carcinoma	p=.016	p=.232	p=.027
Forestomach	0/49(0%)	5/42(12%)	10/49(20%)
Papilloma or Carcinoma	p<.001	p=.018	p<.001
Mammary Gland	0/50(0%)	2/49(4%)	6/49(12%)
Acinar Cell Carcinoma	p=.007	p=.242	p=.012
Ovary: Granulosa Cell	0/49(0%)	6/45(13%)	13/48(27%)
Carcinoma or Tumor	p<.001	p=.010	p<.001

[a] Numerator is number of animals with tumors at the site; denominator is number of animals examined at the site.
[b] The p-value given below the incidence for controls is the p-value associated with the Cochran-Armitage Trend Test.
[c] The p-value given below the incidence for the exposed groups is the p-value associated with the Fisher Exact Test of exposed versus controls.

The most striking of the tumors observed in the mice were the lymphomas and the heart hemangiosarcomas. Malignant lymphoma was the most common tumor type observed in exposed male mice, and these neoplasms were considered to be the major cause of early deaths in both male and female BD-exposed mice. The lymphomas appeared to originate in the thymus of most animals, but NTP noted that their precise origin and pathogenesis were difficult to trace because of their advanced degree of development at the time of necropsy. The lymphomas occurred as early as week 20 in a high dose female, but most deaths attributed to lymphoma occurred between weeks 40 and 45.

The hemangiosarcomas of the heart were of particular interest because these tumors, which occurred with high frequency, are extremely rare in this type of mice. NTP reported that in 2-year studies conducted by the NTP Carcinogenesis Program, only one such tumor has been observed in 2372 untreated male mice of this species and only one such tumor has been observed in 2443 untreated female mice of this species. Heart lesions observed in exposed mice displayed a broad spectrum of changes; changes varied from the presence of more prominent endothelial cells (diagnosed as atypical hyperplasia) to frank tumor masses.

In addition to the malignant lymphomas and the heart hemangiosarcomas, a statistically significant increase in tumor incidence occurred in exposed mice in the lung and forestomach of both males and females, and in the liver, mammary gland, and ovaries of females. Elevated incidences of neoplasms were observed in exposed mice in the preputial gland, brain, and Zymbal gland, but none of these were statistically significant. NTP noted that squamous cell carcinomas of the preputial gland, which occurred in three low dose males and one high dose male, were uncommon in this type of mouse at little more than a year old. Brain neoplasms have been observed in none of 2,343 untreated male B6C3F$_1$ mice in 2-year studies in the NTP Program, but brain gliomas were observed in two low dose males and one high dose male in this study. Carcinomas of the Zymbal gland, occurring in two high dose males and one high dose female, have been observed in only one of 2343 untreated B6C3F$_1$ male mice and none of 2386 B6C3F$_1$ female mice in the NTP Program. Adenosquamous carcinomas of the mammary gland were observed in four low dose females.

Based on the evidence from its inhalation bioassay, NTP concluded there was "clear evidence of carcinogenicity" in male and female

$B6C3F_1$ mice. This category, based on the strength of the experimental evidence, is the highest classification in NTP's system of categorizing evidence of carcinogenicity.

As part of their normal audit procedures, NTP performed an exhaustive audit of the BD bioassay. Initial audit results raised serious concerns about the quality of the study and the interpretation of the study results (Ex. 17–23). These concerns were ultimately resolved after discussions with Battelle Pacific Northwest Laboratories (Ex. 17–24). NTP concluded that the study's deficiencies were either purely administrative in nature, such that they had no effect on the study's results or the interpretation of those results, or were of such small magnitude that they did not affect the overall outcome of the study or the conclusion that BD induced a strong dose-related carcinogenic response in mice (Ex. 22–3, Attachment 4).

In response to concerns raised by the NTP audit, the Chemical Manufacturers Association (CMA) conducted its own audit of the NTP bioassay (Ex. 17–25). In that audit, CMA identified several deficiencies in the conduct of the study. These included inaccuracies in exposure concentration measurements; discrepancies in slide-block comparisons; deviations from study protocol by the testing laboratory personnel; and possibilities of animal mix-ups between exposure groups in the BD study and between study groups from other bioassays running concurrently at Battelle. The audit led CMA to conclude that the BD inhalation study "as reported cannot be certified as a true reflection of the raw data, and cannot be accepted as being in compliance with either the Good Laboratory Practices (GLP) Regulations that were in effect at the time of the study's conduct (Food and Drug Administration, 21 CFR part 58) or the GLP Regulations promulgated by the Environmental Protection Agency (Federal Register, November 29, 1983, part 792)."

NTP addressed the issues raised by the CMA audit in a memorandum to the record dated October 28, 1985 (Ex. 22–3). After responding to each of CMA's specific concerns, NTP concluded:

> It is difficult to understand (CMA's) conclusion regarding certification of the study report. The important question, is the study valid based on a review of the study records and data, seems to be sidestepped by the CMA conclusion which focuses instead on compliance with GLP regulations. It is clear that the NTP and CMA differ in their respective evaluations of the seriousness of their separate audit findings. However, it must be kept in mind that NTP's final conclusion, as stated in Appendix H of its Technical report on 1,3-Butadiene, that is, "the data examined in this audit are considered adequate to meet the objectives of these studies," is based on an in-depth review of all of the available and pertinent records and data in light of the strong biological response obtained by the study * * * Thus, while the NTP study was interpreted on the basis of its own raw data and study records, whatever flaws may have existed did not prevent the correct interpretation of the results.

In its ANPR for BD (51 FR 35003, October 1, 1986), OSHA described a number of the deviations from Good Laboratory Practices that were identified in the NTP bioassay and the Agency's preliminary analysis of the consequences of these deviations on the conclusions reached in the study. Based on this previous analysis and the Agency's review of comments received from the public in response to the ANPR, OSHA continues to agree with the conclusion of the NTP Board of Scientific Counselors' Technical Reports Review Committee that the study conduct had no significant impact on the results or conclusions of the study.

In addition to reviewing the public comment on the ANPR and NTP's response to the CMA audit, OSHA requested that ICF/Clement review the CMA audit and respond to each of the issues raised therein as part of a risk assessment of BD carried out under contract with OSHA (Ex. 23–19). OSHA is satisfied with both NTP's and ICF/Clement's responses to CMA's concerns regarding the BD inhalation bioassay. Although Good Laboratory Practices are important, particularly in studies which form the basis for OSHA regulations, the deviations from Good Laboratory Practices which occurred in the BD inhalation bioassay are not of sufficient magnitude to affect the conclusion that BD caused cancer in these laboratory animals. This position is supported by the preliminary results of a second BD inhalation bioassay recently completed by NTP and reported on by Melnick et al in a paper received by OSHA (Ex. 23–101). The paper presents data which show that the results of this first inhalation bioassay, namely statistically significant excesses of common and uncommon neoplasms in $B6C3F_1$ mice, have been replicated.

(ii) *The IISRP Rat Study.* A two year study of the toxicity and carcinogenicity of BD in rats, sponsored by the International Institute of Synthetic Rubber Producers (IISRP), was conducted by Hazleton Laboratories England (HLE) (Ex. 2–31). The results of this study have been recently published (Ex. 23–84). The exposure groups consisted of 110 male and 110 female Charles River CD rats of the Sprague Dawley strain. The animals were exposed for six hours per day, five days per week to nominal concentrations of 0 ppm, 1,000 ppm, and 8,000 ppm of BD. Actual concentrations averaged 0.7 ppm, 999 ppm, and 7,886 ppm over the course of the experiment. Concentrations of the dimer, 4-vinyl-1-cyclohexene, averaged 413 ppm over the course of the study. When dimer concentrations exceeded 500 ppm, steps were taken to reduce the concentration, but exposure was suspended only when dimer concentrations exceeded 1,000 ppm.

The rats were weighed and palpated for subcutaneous masses weekly. Prior to each exposure session, they were observed for clinical signs of exposure. Between the second and the fifth months of exposure, the rats in the high dose group exhibited signs associated with exposure. These included secretions from the eyes and nares and slight ataxia. After the fifth month of exposure, other clinical abnormalities were recorded, but the study's authors could not attribute them unequivocally to BD exposure.

At 3, 6, and 12 months, blood chemistry, hematology, and urinalysis were performed on a selected group of rats. Again, the authors would not unequivocally ascribe any changes detected in these analyses to BD exposure. After 52 weeks of exposure, ten rats from each sex and dose group were sacrificed. All sixty sacrificed animals were given a post mortem examination, but only rats from the control and high dose groups were given histopathological examinations. The post mortem examinations revealed a significant increase in liver weight between both exposure groups and controls, but the histopathological examinations showed no changes to account for the increase in liver weight. There was no evidence of systemic toxicity in any of the other organs or tissues examined.

The study was terminated at week 111 for the male rats and week 105 for the female rats. Gross necropsies were performed on all animals either sacrificed or found dead. A histopathological examination was performed on all tissues from rats in the high dose and control groups, but for rats in the low dose group, only tissues showing clinical signs at the gross necropsy were originally examined histopathologically. Unexamined tissues were processed to paraffin block stage. A year after termination of the study, IISRP requested that histopathological examinations be conducted on all low

dose group tissues from sites which showed elevated tumor incidence in the high dose group. These sites were the Zymbal gland, thyroid, lung, skin, mammary gland, pancreas, brain, uterus, and testes. In addition, for males only, all kidneys were examined.

Survival among male rats at termination of the study, was 45% for controls, 50% for the low dose group, and 31% for the high dose group. These rates were adjusted for the interim sacrifice at one year. Survival for the high dose males was significantly reduced compared to controls ($X_1^2=4.16$; $p<.025$), but survival for the low dose males was better than survival for the controls. The survival among female rats at termination of the study was 46% for controls, 32% for the low dose group, and 24% for the high dose group. These rates were also adjusted for the interim sacrifice at one year. Survival for both the low dose and the high dose groups was significantly reduced compared to the controls (low dose: $X_1^2=4.12$, $p<.025$; high dose: $X_1^2=10.64$, $p<.001$), but a comparison of the survival functions of the three groups showed that only the survival function of the high dose group significantly differed from the survival function of the control group ($p<.01$).

Volumes III and IV of the HLE report contain pathology reports for every rat in the bioassay. These pathology reports included "cause of illness" or "cause of death" for all rats dying prior to termination of the study. The leading causes of death for male rats were nephropathy and pituitary adenomas. For the female rats, the leading causes of death were mammary tumors and pituitary adenomas. Some of the deaths attributed to mammary tumors occurred in rats with benign mammary tumors.

Overall tumor incidence among male rats was 84% for the controls, 70% for the low-dose group, and 87% for the high dose group, and among female rats was 97% for the controls, 98% for the low dose group, and 94% for the high dose group. Note that not all tissues from low dose animals were examined histopathologically, so the overall incidence for the low dose groups could be an undercount.

Elevated tumor incidence occurred at several different sites. Table 2 presents a summary of the incidence of these tumors. The numbers in Table 2 were derived from the individual pathology reports. Tumor incidence was significantly elevated in high dose male rats at only two sites: the pancreas and the testes. At both of these sites, incidences showed a significant dose-related trend. Gliomas of the brain showed a dose-related trend in male rats, but the trend is not statistically significant. In the original HLE report, these gliomas were divided into three categories, but after reviewing the pathology records on individual rats, it was decided that all these tumors could be grouped together simply as gliomas. Zymbal gland carcinomas neither occurred at a significantly elevated rate nor showed a dose-related trend, but these tumors are rare and thus are presented.

TABLE 2.—SUMMARY INCIDENCE OF PRIMARY TUMORS IN CHARLES RIVER CD RATS INDUCED BY INHALATION OF 1,3-BUTADIENE [a]

	Controls	1,000 ppm	8,000 ppm
Males:			
Pancreas: Exocrine	3/100	1/100	11/100
Adenoma or Carcinoma	p<.01[b]	p=.939[c]	p=.025[c]
Testes	0/100	3/100	8/100
Leydig Cell Tumor	p<.01	p=.123	p=.003
Brain: Glioma	1/100	3/100	5/100
	p<.10	p=.311	p=.106
Zybal Gland	0/100	1/100	1/100
Carcinoma	p<.50	p=.500	p=.500
Females:			
Thyroid: Follicular	0/100	4/100	11/100
Adenoma or Carcinoma	p<.001	p=.061	p<.001
Mammary Gland	40/100	75/100	67/100
Fibroadenoma	p<.001	p<.001[d]	p<.003[d]
Uterus/Cervix	1/100	4/100	5/100
Stromal Sarcoma	p<.25	p=.184	p=.106
Zymbal Gland	0/100	0/100	4/100
Carcinoma	p<.025	p=1.0	p=.061

[a] Numerator is number of animals with tumors; denominator is number of animals examined at the site. It is assumed that all animals were examined at each site.
[b] The p-value given below the incidence for controls is the p-value associated with the Cochran-Armitage Trend Test.
[c] The p-value given below the incidence for the exposed groups is the p-value associated with the Fisher Exact Test of exposed versus controls.
[d] Fisher Exact Test approximated by a Chi-square Test for Independence. For controls versus low dose, $X^2_1=25.06$; for controls versus high dose, $X^2_1=14.65$.

In female rats, significantly elevated tumor incidence also occurred at only two sites: the thyroid and the mammary gland. At both of these sites there was a statistically significant dose-related trend. Elevated tumor incidence occurred in the uterus/cervix and the Zymbal gland as well, but in neither of these cases was the increase statistically significant. The incidence of Zymbal gland carcinomas was nearly significant ($p=.06$), and there was a significant dose-related trend ($p<.025$).

The majority of mammary tumors observed in the female mice were mammary fibroadenoma. Many experts believe that mammary fibroadenomas represent a carcinogenic response although these tumors are not in and of themselves carcinogenic. For example, in their system for categorizing evidence of carcinogenicity, NTP holds that the category "Clear Evidence of Carcinogenicity", the strongest of the categories, may be demonstrated by a "substantially increased incidence of benign neoplasms." NTP applied this criterion in evaluating results from an inhalation bioassay of methylene chloride involving F344/N rats. In that evaluation, NTP concluded there was "clear evidence carcinogenicity for female rats as shown by increased incidence of benign neoplasms (fibroadenomas) of the mammary gland" (Ex. 7–008). Nevertheless, some argue that because these tumors occur at a high background rate and are not known to become malignant, their relevance is uncertain.

There can be no doubt that there was a substantially increased incidence of mammary fibroadenomas in the exposed female rats in the HLE study. The low dose group had an 88% increase in incidence over controls, and the high dose group had a 68% increase in incidence over controls. These increases

are statistically significant ($p<.003$). Not only was an increase in incidence of benign mammary neoplasms observed, but an increase in the number of tumors per tumor bearing rat was also observed in the exposed groups. An increase in the number of mammary tumors per tumor bearing rat provides additional evidence to denote the relative strength of the carcinogenic stimulus (Ex. 23–25). Table 3 presents the number of mammary fibroadenomas observed in all female rats. Although an increase in the number of tumors per animal cannot be quantified in mathematical dose-response models, they give further support to the position that BD is a carcinogen in rats.

TABLE 3.—NUMBER OF MAMMARY FIBROADENOMAS OBSERVED IN FEMALE CD RATS EXPOSED TO 1,3-BUTADIENE

No. of mammary fibroadenomas per female rat	Number of female rats		
	Controls	1000 ppm	8000 ppm
0	60	25	33
1	28	25	19
2	9	11	15
3	3	9	7
4	0	6	8
5	0	4	5
6	0	5	3
7	0	4	5
8	0	4	4
9	0	2	0
10	0	4	0
11	0	1	1
Total number of tumor-bearing rats	40	75	67
Average number of tumors per tumor-bearing rat	1.38	3.70	3.33

Nephropathy, or degeneration of the kidneys, was the most common non-carcinogenic effect reported for male rats and was one of the main causes of death for the high dose males. The incidence rates of nephropathy are presented in Table 4. The combined incidence of marked or severe nephropathy is significantly elevated in the high dose group over incidence in the low dose group and over incidence in the controls ($p<.001$). HLE's analysis of "certainly fatal" nephropathy shows a significant dose-related trend ($p<.05$), but when "uncertainly fatal" cases are included, the trend disappears.

TABLE 4.—INCIDENCE OF NEPHROPATHY IN MALE CD RATS EXPOSED TO 1,3-BUTADIENE

Degree of nephropathy	Controls	1000 ppm	8000 ppm
None	13/100	25/100	9/100
		p=.03 [a,b]	p=.36 [a]
Minimal	29/100	32/100	11/100
		p=.65	p<.01
Slight	38/100	27/100	42/100
		p=.10	p=.57
Moderate	10/100	7/100	11/100
		p=.45	p=.82
Marked	3/100	3/100	14/100
		p=1.0	p=.01
Severe	7/100	6/100	13/100
		p=.78	p=.16

[a] The p-value is associated with a Chi-square approximation of the Fisher Exact Test (exposed versus controls).

[b] Incidence of no nephropathy is significantly higher among low dose males over control males.

The HLE study authors concluded that the interpretation of the nephropathy incidence data was equivocal. They stated that "an increase in the prevalence of the more severe grades of nephropathy, a common age-related change in the kidney, was considered more likely to be a secondary effect associated with other unknown factors and not to represent a direct cytotoxic effect of the test article on the kidney."

Other non-carcinogenic effects observed in the HLE rat study were elevated incidence of metaplasia in the lung of high dose male rats killed at the end of the study over incidence in male controls killed at the end of the study (10/31 vs 5/45), and a significant increase in high dose male rat kidney, heart, lung, and spleen weights over the organ weights in control male rats ($p<.05$ for all but the kidney where $p<.01$).

The HLE study authors concluded that BD is "associated with 44 statistically significant increases in both common and uncommon tumor types." Although the authors found the biological interpretation of some of these data equivocal, they nonetheless concluded that based on the weight of the evidence, BD is an oncogen which elicited a weak response in the rat.

OSHA agrees that BD is carcinogenic in rats but is concerned about certain issues which arose in its analysis of the HLE study and which may affect the interpretation of the study. The first of these is that there appears to have been a failure in the randomization process, for the male rat groups do not seem to be comparable. Specifically, the low dose male rats appear to have been healthier than the male rats in the control group. The low dose males had an overall tumor incidence of 70% which is significantly lower than the 84% overall tumor incidence observed among the male controls ($X^2_1=5.53$, $p<.05$). Although this difference could be due to the fact that not all tissues were examined from the low dose males, OSHA notes that not all tissues were examined for the low dose females, yet the overall tumor incidence for that group was the same as for the female controls.

The nephropathy incidence data give further evidence that the male rat groups were not comparable. The HLE study authors concluded that there was no difference in nephropathy incidence between control and low dose males. OSHA, however, finds this conclusion to be erroneous. HLE looked only for significant excess of nephropathy in the low dose group. If nephropathy is an age-related condition, one would expect to see more low dose males with some degree of the condition because the low dose males lived longer. Instead, only 75% of the low dose males had any degree of nephropathy whereas 87% of the controls had some degree of the condition ($p=.03$). This suggests that the low dose males were less susceptible to kidney degeneration than the controls which, in turn, implies that the two groups were not comparable.

The low dose male rats also differed from the other groups of rats in the number from that group which had "abnormal teeth." Nine low dose male rats were sacrificed because of abnormal teeth, while in the other groups, the numbers sacrificed for this reason were: four in the male control group; three in the male high dose group; three in the female high dose group; and none in either the female low dose group or the female control group. The incidence of sacrifice because of abnormal teeth in the low dose male group was significantly elevated over the incidence of sacrifice because of abnormal teeth in every other sex/dose group except the male control group, where it approached significance ($p=.125$). This difference furthers the concern that the low dose male rats were not comparable to the other rat groups.

In addition to its concern about the lack of comparability among male rat groups, the Agency is concerned about the adequacy of the study audit to which this bioassay was subjected (Ex. 28–19). Slide-block comparisons were made for only ten out of 600 animals (2%). In the NTP study, slide-block comparisons were made for all control and high dose animals. The study auditors were unable to locate raw data sheets for 74 (12%) of the study animals. Therefore it was impossible to verify the study's final report as an accurate reflection of the raw data.

OSHA is aware that the HLE study, which began in 1977, was performed in accordance with the Good Laboratory Practice regulations in place at that time. While the Agency does not believe that the study is fatally flawed, it is concerned about the issues discussed above. Nonetheless, the Agency believes that the HLE study demonstrates the carcinogenicity of BD in rats.

2. Epidemiologic Studies

Evidence of an association between occupational BD exposures (BD) and cancer mortality is found in studies of BD monomer production workers (Downs, Ex. 17–33), styrene-butadiene rubber workers (SBR), (Meinhardt, Ex. 2–26; Matanoski, Ex. 2–27; McMichael, Exs. 23–4 and 23–41), and SBR production workers in the rubber industry (general/SBR), (Andkelkovic, Exs. 23–27 and 23–3). What is most striking about these studies is the consistency of the observed elevated incidence of lymphomas, leukemias, and other neoplastic diseases of the hematopoietic system among BD workers.

OSHA evaluated these five studies which have also been reviewed by the International Agency for Research on Cancer (IARC) (Exs. 23–31 and 23–32), ICF/Clement (ICF) (Ex. 23–19), the Chemical Manufacturers of America (CMA) (Exs. 17–31 and 28–14), and the International Institute of Synthetic Rubber Production (IISRP) (Exs. 17–28 and 17–32).

In these epidemiological studies, increased risk of death is measured by the standardized mortality ratio or SMR. An SMR is the ratio of the observed number of deaths to the expected number of deaths multiplied by 100. The relevance of the SMR depends upon the choice of the standard population from which we expected the number of deaths is derived. For instance, one worker population should experience SMRs similar to another worker population while the general population, which includes sick and disabled or institutionalized persons, usually experiences greater mortality risk. Active workers must be healthy enough to have been, and to remain, employable. Populations of active industrial workers have been estimated to experience a mortality risk of 60% to 90% (SMR=60 to 90) of that found in the general population (McMichael, 1976, Ex. 23–40). This lowered mortality risk among industrial workers is known as the "healthy worker"effect.

In assessing the association between BD exposure and cancer death, the rate of death in the exposed group is evaluated to determine whether it differs from the rate of death in the nonexposed group and if so, whether this is due to chance or cause. Because of the inherent variability in biologic systems, the rate of cancer in one group of workers exposed to a carcinogen will often differ slightly from the rate in a second group exposed in a similar manner simply by "chance". If the rates of death differ greatly, tests of statistical significance provide an estimate of the probability that the result could have arisen by chance alone or is due to a causal association. When an SMR is significantly elevated, this means that there is little probability that an observed association between exposure and death is due to chance alone.

Tests of statistical significance, however, can be misinterpreted. The p-value used in these studies represents the probability that an observed excess of cancer deaths occurred by chance alone. When the p-value is smaller than some value, usually .05, we conclude that an observed result could not be due to chance alone and must therefore be due to BD exposure. This choice of significance level is arbitrary and should not be taken alone as evidence of a meaningful excess or a non-excess of cancer mortality. An observation of no significant increase in a specific cause of death at the .05 level in a study may indicate no association, but it may be due to other factors such as a small sample size or other methodologic limitations. Likewise, a significant increase at the .05 level in a site-specific cause of death does not necessarily mean that there is a causal association.

Below is a brief description of each of the studies and the various comments and criticisms put forth by the reviewers. OSHA reviews these data together in part (d) of this epidemiology portion and presents a summary of the studies in part (e).

(i) *Workers Engaged in BD Monomer Production.* Downs et al. followed a cohort of workers with primarily BD exposures. Cause-specific mortality in the 2,586 male workers employed in BD monomer producing plant at least six months between 1943 and December 31, 1979 was examined. The study plant was one of three facilities built during World War II in Port Neches, Texas (Neches Butane). Other products, such as isobutylene polymers and isoprene, are produced in this plant. Qualitative exposure data were available. There were 603 deaths that were known to have occurred in the cohort through 1979. Death certificates were obtained for all but 24 (4%). Of the remaining 1,983 persons in the cohort, the vital status of 73 (2.8% total) was unknown.

SMRs for all lymphohematopoietic cancer (All LHC) and for different types of lymphohematopoietic cancer (LHC) in the total cohort are included in Table 5. The types of LHC in the group "All LHC" are lymphosarcoma/reticulosarcoma (LSC/RCS), Hodgkin's Disease (HD), multiple myeloma (MMY), leukemia, and other specified lymphoma (non-Hodgkin's Disease lymphoma (NHL)) in both the seventh and eighth revisions of the International Classification of Diseases (Ex. 23–34) and polycythemia vera (PV) and myelofibrosis (MF) in the eighth revision. The SMR for lymphosarcoma/reticulum cell sarcoma (LSC/RCS) is significantly elevated for the total cohort.

TABLE 5.—SMRs for LHC in BD Monomer Facility, Total Cohort

Type of cancer [a]	SMR	Observed
All Causes	*80	603
All LHC [b]	143	21
LSC/RCS [c]	*235	8
Hodgkins Disease (HD)	102	2
Other	124	4
Leukemia	119	7

*p less than 0.05.
[a] International Classification of Diseases, Eighth Revision (ICDA.–8, Ex. 23–34).
[b] LHC-all lymphohematopoietic cancer, ICDA.–8. Nos. 200–208, no myelofibrosis (MF, ICDA. No. 209).30:
[c] LSC/RCS-lymphosarcoma/reticulum cell sarcoma, ICDA.–8. No. 200.
[d] Other—includes other (ICDA.200), multiple myeloma [(MMY)ICDA.203], and polycythemia vera [(PV), ICDA.208].

A qualitative scale for exposure to BD was constructed based on an employee's function at the plant and level of exposure. Four groups were developed: Low exposure, routine exposure, non-routine exposure, and unknown exposure. Workers in the low exposure category were exposed to low levels of BD on a non-routine basis. Workers in the routine exposure category had high BD exposures on a routine basis. Workers in the non-routine exposure category had the highest BD exposures but on a non-routine basis. It is noteworthy that elevated LHC SMRs were observed in all three occupational function groups with known BD exposures. These results are presented in Table 6.

TABLE 6.—SMRs FOR LHC BY OCCUPATIONAL GROUPS

Exposure group	Type of cancer	SMR	Observed
Low [a]	All LHC	128	3
	LSC/RCS and other [b]	190	2

TABLE 6.—SMRs FOR LHC BY OCCUPATIONAL GROUPS—Continued

Exposure group	Type of cancer	SMR	Observed
Routine [a]	All LHC	187	6
	LSC/RCS and other [b]	282	4
Non-routine [a]	All LHC	167	10
	LSC/RCS and other [b]	150	4
	Leukemia	201	5

[a] Low=low exposures on a non-routine basis; routine=high exposures on a routine basis; non-routine=highest exposures on a non-routine basis.
[b] ICDA.-8 Numbers 200,202,203,208,209 [non-Hodgkin's lymphoma (NHL), multiple myeloma (MMY), lymphosarcoma/reticulum cell sarcoma (LSC/RCS), myelofibrosis (MF), polycythemia vera(PV)].

In general, research on BD has focused only on qualitative estimates of exposure and associated relative risks of death from specific cancers. In order to strengthen these qualitative risk estimates, OSHA has attempted to evaluate workers' exposures to BD in relation to relative risk of death from all LHC using job titles. Since the cohort studied by Downs was exposed primarily to BD, this grouping of workers is likely to yield the most specific BD related exposure data.

Downs selected sub-groups of the study population with more or less uniform exposure, or at least the same pattern of exposure, such as working in a particular department, or process, or a particular job category, or some other suitably defined group in which the level and frequency of exposures are thought to be roughly the same for everybody. In the Downs study, classification of workers was conducted by the researchers after consultation with the staff at the plant and before analysis of the data was undertaken. The original paper provides additional detail for qualitative exposure assessment.

For OSHA's analysis, exposure, the principal independent variable, consists of categories of job titles (with their exposure ratings and frequency of BD exposures). An exposure level rating (ER) from 1 to 4 was assigned to each job title category based on the author's description of exposure levels. An ER=1 is a low BD exposure (BD not in usual work area and not handled by worker); ER=2 is medium exposure (BD in work area but employees do not handle); ER=3 is high exposure (BD exposure levels in work area are high but worker doesn't handle BD); ER=4 is the highest exposure (intimate, very high, inhalation and dermal exposure, workers handle BD). Handling BD involves a high potential for inhalation of high concentrations of BD or for skin contact with BD. Each job category was assigned a value indicating the frequency of BD exposure, based on the authors' descriptions. Frequency factors (F) were: 1—infrequently exposed; 2—occasional but regular exposures (non-routine); and, 3—routine and continuous exposures. An Exposure Value (EV) was assigned to each job group by multiplying the (ER) by (F). Exposure Value=(Exposure Rating) ×(Frequency Factor), or EV=(ER)×(F). The EVs by job group are shown in Table 7.

TABLE 7.—EXPOSURE VALUE BY JOB GROUP, BY STUDY

Exposure description	Study job group: Downs	(ER)×(F)=EV	Relative EV*
Low; Non-Routine	Low	(1)×(2)=2	1
Highest; Non-Routine	Non-Routine	(4)×(2)=8	2
High; Routine	Routine	(3)×(3)=9	3

*Relative EV: lowest EV per job group has relative EV=1; highest Ev=total number of job groups.

The EV allows the comparison of groups of workers by relative exposure, that is, the lowest EV is the lowest relative effect. Relative exposure is being compared with relative effects, the dependent variable. The principal effect under consideration is death from all lymphohematopoietic cancer measured by SMRs. The degree of concordance between relative EVs and SMRs for all lymphohematopoietic cancer indicates that an increase in BD exposure, approximated by job category, is producing a real increase in SMRs for All LHC. (See Table 8).

TABLE 8.—THREE PAIRS OF VARIABLES

[EVs and associated SMRs for all lymphohematopoietic cancer]

Relative EV	Job group	EV	SMR
1	Low	2	128
2	Non-routine	8	167
3	Routine	9	187

CMA put forth several criticisms of the Downs report. One of these is that the lymphohematopoietic cancers represent a heterogeneous group of diseases whose etiologies are uncertain. However, on the basis of the difficulty of distinguishing these diseases clinically from each other, there is general agreement in standard medical textbooks that the diseases in this group may represent progression from one to another stage of the same disease in one individual (Gunz, Ex. 23-30; Jaffe and Costan, Ex. 23-35; Wintrobe, Ex. 23-47).

Furthermore, recent studies using chromosomal banding (Kersey, 1983, Ex. 23-37; Yunis, 1983, Ex. 23-48; Bloomfield et al., 1978, Ex. 23-29) indicate that leukemia can result from a genetic lesion to or transformation in the genetic material of, the primitive stem cell that can differentiate into any of the blood cells. Therefore, any form of leukemia, lymphoma, or possibly NHL/MMY may be possible as a result of exposure to a cancer-causing substance. For the above mentioned reasons, the group "All LHC" seems reasonable for use in analysis.

Some criticism was raised by CMA (Ex. 28-14) that SMRs for leukemia were elevated in the non-routine group of workers and not in the routinely exposed group. Commentors were of the opinion that this observation suggested no association with BD exposures. The total cumulative dose of BD from short term exposures among non-routinely exposed workers, however, may have exceeded the total cumulative dose of BD among routinely exposed workers thereby leading to greater dose. This would be true in situations in which high short-term exposures to a substance are related to increases in death from a specific cancer while lower routine exposures are not. In terms of dose-response, short-term high doses of BD may be more relevant to leukemia than routine exposures. SMRs for LSC/RCS are elevated among routinely exposed workers above low and non-routinely exposed workers. It appears as though there may be an association between

routine BD dose and LSC/RCS response. In either case, frequency of dose is one of the main issues.

Two problems inherent in any occupational mortality statistics are sample size and misclassification of employee. In the Down's study, the number of workers in each job subgroup was adequate for analysis by OSHA. Of the total 603 deaths in this cohort, 89 were in the low exposure group, 108 were in the routine exposure group, and, 273 were in the non-routine exposure group. The remaining 133 deaths were among workers who were not classifiable as to exposure category. Small numbers of workers in each job subgroup result in lower power to detect increased health risk and may bias the study results in the direction of finding no association. Nevertheless, it appears as though SMRs for ALL LHC and LSC/RCS increase as routine BD exposure increases. Downs, as well as other researchers, has drawn inferences from this data.

Misclassification of workers would tend to obscure relationships between BD exposure and cancer. This is because workers with exposure frequencies and levels that are associated with a specific cancer might be included in another exposure group, resulting in excess cancer death in this latter group. The fact that Downs found elevated SMRs for LSC/RCS among employees in the total cohort and for ALL LHC in workers in each subgroup with known BD exposure, despite problems that would obscure any such relationship, strengthens the evidence of risk of these cancers being associated with BD.

(ii) *Workers Engaged in Styrene-Butadiene Rubber (SBR) Production.* Industrial hygiene monitoring data show detectable levels of BD among various production, processing, and maintenance jobs in SBR manufacturing (Ex. 17–27). OSHA considers it to be of value to review studies of SBR workers to evaluate SBR-related mortality excesses separately from mortality excesses among BD monomer production workers, since the latter employees are the most likely to have experienced primarily BD exposures.

Studies of workers in SBR facilities were conducted by three researchers (Meinhardt et al.; Matanoski et al.; and, McMichael et al.). Matanoski stated that,

> The synthetic rubber industry did not exist until 1943. At that time the federal government undertook to construct 15 plants in the U.S. all of which had similar design and all of which were committed to the manufacture of styrene BD rubber. An additional plant was constructed at that time in Canada. The general construction of the plants as well as the basic processes used in these plants were similar * * * it is these U.S. plants and one in Canada with which NIOSH (Meinhardt) and the current study (Matanoski) have been concerned. Over time these companies have begun to manufacture various other types of rubber but, in general, their major product is still styrene BD rubber. The workers exposed to these substances should have been relatively young at the time of first start in the new industry and should have had no previous exposure to synthetic rubber polymer manufacturing processes. Two major changes took place in most of the plants in the early operations. These were a change from batch to continuous feed manufacturing process and the addition of low-temperature rubber production. Cold rubber production was begun in the late 1940's to early 1950's in most plants (Ex. 23–39).

Because employees had limited exposure to other substances, the SBR studies are particularly useful in assessing employees' risks from exposure to BD.

Meinhardt et al. reported the results of a retrospective cohort mortality study conducted at two adjacent SBR facilities in Port Neches, Texas, (plant A, B.F. Goodrich and plant B, Firestone/U.S. Rubber Co.). Workers in plants A and B were followed from January 1943 and January 1950, respectively, to the study cutoff date of March 31, 1976. The study cohorts from plants A and B consisted of 2,756 white males who had at least 6 months non-management and non-administrative employment. While the study was being conducted in 1982, a limited number of environmental samples were obtained at each plant. Historical monitoring data were not available for either plant. The SMR for all causes of death for plant A was 80, (252 Obs, 315 expected deaths), and for plant B was 66 (80 Obs, 115 expected deaths).

Workers were counted as cases in the cohort analysis if: (1) They were employed more than 6 months; (2) they died within the cohort study date; (3) cancer was coded as the underlying cause of death; and (4) they were white males. In plant A, five deaths from leukemia were included in the mortality analysis. Six other workers with leukemia were excluded from analysis because they did not fit the cohort definition. Two of these six workers were excluded because they had worked less than six months; another two workers were excluded because they were alive at the time of the reporting of the study results. A fifth worker died of leukemia after the study cut-off date, and the sixth worker was non-white.

For cohort B, there was a significant deficit of mortality from all malignant neoplasms. One leukemia death was included in the mortality analysis. Three other individuals employed in the plant and diagnosed with leukemia were excluded from the analyses because they did not fit the cohort definition. For two of these workers, leukemia was not coded as the underlying cause of death by the nosologist. The third worker with leukemia was alive at the time of the reporting of the study results.

The likelihood of detecting a 2-fold relative risk of leukemia was 26% for cohort A and 13% for cohort B. Thus, if excess leukemia risks were less than two times that of the general population, the probability of detection was very low.

Both CMA (Ex. 28–14) and IISRP (Ex. 17–28) stated that the Meinhardt study found no statistically significant excess in total mortality or cause-specific mortality in the total cohort. However, OSHA notes that statistically significant excesses were observed for leukemia using a one-sided test, the methodology OSHA believes is appropriate in an occupational study. The authors stated regarding the use of the two-sided test statistic that it is:

> "conservative in its ability to detect significant differences, if there is no reason to believe the environment would be protective against cause specific mortality (acknowledging the operation of the employment selection bias known as the healthy worker effect). Historically, it was the custom at the National Institute for Occupational Safety and Health to use the conservative two-sided test statistic. Prior to and at the time this report was prepared and originally presented, two of the authors were debating the relative merits of one-sided versus two-sided test statistics. Although we subsequently agreed that the one-sided test statistic was more appropriate for tests of a specific hypothesis about a potential excess risk of cause-specific mortality we have left the two-sided test statistic in this paper since the results had already been presented in that way (Ex. 2–26)."

Some (Ex. 28–14) have stated that the excesses of death in the war cohort (subcohort Plant A, employees who worked 6 months or more in plant A between January 1, 1943 and not after 1945) were not observed in plant B. Comparable mortality analyses, however, could not be made between a "war cohort" in plant A and Plant B, since personnel records for workers in plant B were not accessible for the years 1943 to 1947.

Some (Ex. 28–14) have argued that BD could not have caused the leukemia deaths observed in the study because the leukemia cases were of different cell

types and therefore were not of common etiology. As stated previously, recent studies using chromosomal banding suggest that leukemia is the result from a genetic lesion or the transformation in a primitive stem cell (Kersey, 1983, Ex. 23–37; Yunis, 1983, Ex. 23–48; Bloomfield et al., 1978, Ex. 23–29). Since this cell can differentiate into any of the blood cells, any cell type of leukemia should be possible as a result of exposure to a leukemia-causing substance. In addition, while leukemia is one of the more accurately reported causes-of-death on a death certificate, changes have occurred in the way physicians diagnose cell type, i.e. in differential diagnoses. For all these reasons, OSHA is persuaded that leukemia need not have a common cell type to be significant and that the broad category of "leukemia" provides sufficient detail for the purposes of these analyses.

Others have commented that there was insufficient latency (3 years) for two leukemia cases in plant A, and therefore these two leukemia cases were probably not related to BD exposures. OSHA believes that the range of latency periods for leukemia is not inconsistent with the latencies observed in Meinhardt's Plant A. The period, between exposure to the carcinogenic stimulus and appearance of the clinically diagnosable cancer, is called the latent period. It is a summation of the time periods required for the initiation of the malignant change, and for growth to a stage that permits recognition and diagnosis.

The median latency period in Hiroshima for radiation-induced leukemia was five years (Ex. 23–81). Thus, one would expect that individuals would have both longer and shorter periods of latency. With benzene exposure, some leukemia deaths appeared within a period of a few years from initial exposure (Ex. 23–82). Thus, it would appear as though a latency period of three years observed by Meinhardt, is within the range reported for known causes of leukemia.

Another criticism of the study was that multiple exposures occurred and that current BD levels at Plant B are higher than at Plant A, and, thus, a higher incidence of BD-associated disease should have been observed in Plant B. OSHA is of the opinion that current exposure levels in these plants do not necessarily reflect past exposure levels due to process and sampling changes. Thus, these current exposure data could be unreliable for use in determining a dose-response. Instead, calendar time, when BD exposures were known to be relatively higher due to the use of different processes (hot batch versus cold process), can be substituted. Since workers who worked in hot batch polymerization processes probably experienced the highest relative BD exposure among workers in this cohort, excesses of BD-associated death would more likely be observed among the "war-cohort" workers. The only report on mortality among hot batch polymerization workers is provided by Meinhardt et al., who observed that all five individuals from plant A whose underlying cause of death was leukemia began employment before the end of December 1945. Therefore, the mortality experience of 600 white males "war-cohort" employees who are a subcohort of Plant A was analyzed separately. These employees worked 6 months or more in plant A between January 1, 1943, and the end of December 31, 1945, (and not after 1945) in hot temperatures, batch polymerization processes. At that time, working conditions were less well controlled than modern day practices due to the urgent wartime need for synthetic rubber.

The overall SMR of 83 for all causes of death among war-cohort employees was similar to that for the entire cohort from Plant A (overall SMR–80). Noteworthy SMRs for malignant neoplasms of lymphatic and hematopoietic tissues in the war cohort of plant A, which was a hot batch process, are included with SMRs from the cold process workers of plant B in Table 9. As can be seen, SMRs for ALL LHC, LSC/RCS, Hodgkins Disease, and leukemia are higher among the hot batch process workers.

TABLE 9—DEATH RATES BY CALENDAR TIME PERIOD (PROCESS), MEINHARDT STUDY

[Calendar Time Period (PROCESS)]

Cancer type	War Years (HOT)[a]			Post War Years (COLD)[b]		
	SMR	Observed	Exposed	SMR	Observed	Exposed
All LHC	*212	9	4.25	78	2	2.5
LSC/RCS[c]	224	3	1.34	132	1	0.8
H.D	213	1	0.47	0	0	0.3
Leukemia[d]	*278	5	1.80	100	1	1.0

*Significant Excess, p less than 0.05, one-sided test.
[a]Plant A subcohort.
[b]Plant: B.
[c]Includes only ICD-7 Number 200 for lymphosarcoma/reticulum cell sarcoma.
[d]The five cases of leukemia were: chronic myeloid (2 deaths), myelogenous (unspecified as to acute or chronic), acute myeloblastic, and acute lymphoblastic.

There is a possibility that this observation may be the result of a generalized exposure in the SBR industry. However, in order to affect the incidence of LHC, this generalized exposure would have to increase and decrease over time in the same way and magnitude that BD exposures change. The presence of a generalized exposure would not rule out the contribution to cancer death excess caused by BD exposure.

IISRP (Ex.17–28) suggested that the Meinhardt study was biased toward finding excess leukemia because it was undertaken following a report of two leukemia deaths at these facilities, as opposed to a study conducted in a similar plant chosen at random. ICF (Ex. 23–19) pointed out, however, that the chance observation of the sentinel health event (two leukemia deaths in adjacent SBR facilities) by the astute clinician has historically served as the impetus for the initial investigation of many now commonly accepted occupational diseases. The investigators are able to minimize bias by choosing to investigate the mortality rates for *all* employees with at least six months of non-administrative employment, and then comparing these rates to age, race, calendar time, and cause-specific mortality rates in the overall U.S. population. ICF stated:

> Of more importance than selecting a "cluster" of disease, with respect to the selection of the study participants, is the dilution of the "true" study population, specifically those workers with significant occupational exposures, with employees who worked in non-hazardous areas of the plants

or worked primarily in administrative positions.

Thus, the chances are that this study might have masked such an association. In summary, OSHA is of the opinion that this study adds meaningful evidence to an association between exposure to BD and All LHC.

In a second study of SBR workers, Matanoski et al., 1982, first reported the mortality experience of individuals employed in seven U.S. and one Canadian styrene BD rubber (SBR) plants. These plants were not identified by name by the study authors. The study population consisted of males who had worked at these plants for more than one year. Statistical analyses were conducted on data from work records for each employee from the time each company's recordkeeping system became complete.

Vital status was determined through 1976. The total study population was 13,920. Out of eight separate plant cohorts, four (plants 3,6,7, and 8) were followed from 1943. In these plants, more than half of the original worker population was excluded from analyses due to incomplete records. In the remainder of the plants, follow-up starting dates were: Plant 5, 1953; plant 2, 1958; plant 1, 1964; and plant 4, 1970. The start-up date for each of the latter four plants was different, and thus the follow-up time for workers at each plant was different. In these latter plants, 30 to 56% of the original worker population was excluded. Thus, most of the employees from plants 1, 2, 4, and 5, were not followed long enough for complete evaluation of carcinogenic risk, and OSHA is concerned about selection bias in the former four plants, which would have excluded many workers who worked in 1943 when there were relatively higher BD exposures.

The SMR for all workers at all plants for all causes of death was 81; the SMR for black workers was 98, and for whites the SMR was 78. The average age at death was 62 years. No specific causes of death were significantly elevated.

Power calculations were performed to test the ability of the data to determine increases in risk greater than the U.S. population. Most cancer risks less than two times that of the general population would have a low probability of detection even with this large population of workers. For instance, the probability of detecting a 50% increase in leukemia (SMR=150) was .62, while the probability of detecting such an increase in kidney cancer or other lymphatic cancer was about .45.

CMA (Ex. 28–14) stated that the power of the Matanoski study greatly exceeded that of the Meinhardt study, and therefore the Matanoski study should receive correspondingly greater weight for risk assessment purposes. This statement indicates a misunderstanding of power. The power of a study relates to the ability of a study to detect an effect. There are factors that affect the ability to detect an effect. The Matanoski study did not show any overall site-specific cancer to be in significant excess. Hence, the power of the study to detect elevated risks of site-specific cancer death was calculated, and it was determined that the probability of detecting elevated cancer risks was low. When a study indicates an increased risk of a particular cause of death, a power calculation is not necessary as the ability of the study to detect such an excess is not an issue.

Analysing these data, EPA (Ex. 17–27) found several limitations that could lead to an underestimate of the cancer risks to BD employees including exclusion of over half the original cohort, misclassification of living employees, insufficient latency, low power to detect increased cancer risk, and lack of historical exposure

CMA (Ex. 28–14) commented that the bulk of the excluded workers were short-term employees, probably workers employed during the war years (1943–45) and therefore the least likely to be affected by BD exposure. OSHA agrees that the study excluded many employees who worked during the war years, but OSHA disagrees with the conclusion that these workers had the least BD exposures.

Studies of other industrial cohorts have shown a relatively higher risk of death for the disease known to be related to the substances under study among short term workers (Infante and Schneiderman, 1986, (Ex. 23–33)). Any one group that is systematically under-represented can alter the findings and conclusions of the study. In an effort to investigate cancer etiology, inclusion of all groups in which there is some evidence of a possible association is preferable, and the exclusion of such workers from a cohort may bias the results toward finding no association. OSHA believes that although the effect of the exclusion of "early workers" is not known, it is reasonable to assume that the loss of their data reduces the chance of identifying relationships between BD and disease.

Subsequent to OSHA's publication of an Advance Notice of Proposed Rulemaking, Matanoski updated the original study by following workers for three additional years, (Ex. 2–27). The total population included 12,107 male workers, and all analyses were adjusted to include only workers who were 45 years of age or older and who had 10 years of SBR employment. For specific details, readers are referred to the original paper. Mortality was analyzed by four job categories: production, maintenance, utilities, and other. The elevated LHC cancer SMRs among production workers are included in Table 10.

TABLE 10.—SMRs AMONG ALL (WHITE AND BLACK) PRODUCTION WORKERS

Cancer type	SMR	Observed	Exposed
All LHC	146	19	13.0
LSC/RCS	038	1	2.6
Hodgkins disease	120	2	1.7
Other*	**260	9	3.5
Leukemia	142	7	4.9

* Other excludes: LSC/RCS, HD, and leukemia.
** p=.02, two sided test.

One of the major findings of the Matanoski follow-up study was a significantly elevated SMR for "other LHC" among production workers (9 Observed vs. 3.5 Expected, SMR=260, 95% CI 1.2–4.9, p=0.02) reflecting excesses for both black and white employees. In addition, SMRs for non-white production workers were significantly elevated for leukemia (3 observed vs. 0.42 expected, SMR=710, 95% CI 1.5–20.9, p=0.01) and for all LHC (6 observed, vs. 1.2 expected, SMR=504, 95% CI 1.8–11.0, p=0.003). Production workers, who had the highest relative continuous BD exposures, had an SMR of 146 for all LHC. Utility workers (SMR=203) had highest BD concentrations on a non-routine basis.

Matanoski identified employees by work areas who were most likely to have experienced relatively higher BD exposures and selected sub-groups of the study population with more or less uniform exposure. Patterns of exposure are thought to be roughly the same for everybody. Workers were classified into four major categories: maintenance, production, utilities, and unknown. OSHA evaluated SMRs by three of these four general work areas in order to strengthen the qualitative risk estimates, as was done by OSHA in the Downs study.

As stated previously, the principal independent variable, consists of categories of job titles in work areas (with their exposure ratings and frequency of BD exposures). The same exposure level rating system used in the Downs' study, (ER) from 1 to 4, was assigned to each category based on the author's description of exposure levels. Each category was assigned a value

indicating the frequency of BD exposure, based on the authors' descriptions. Frequency factors (F) were: 1-infrequently exposed; 2-occasional but regular exposures (non-routine); and, 3-routine and continuous exposures. An Exposure Value (EV) was assigned to each job group by multiplying the (ER) by (F). Exposure Value=(Exposure Rating)×(Frequency Factor), or EV=(ER)×(F). The EVs by job group are shown in Table 11.

TABLE 11.—EXPOSURE VALUE BY JOB GROUP, BY STUDY

Study Job Group			
Exposure description	Matanoski	(ER)×(F)=EV	Relative EV
Low; Infrequent.	Maintenance.	(1)×(1)=2	1
Medium; Routine.	Production..	(2)×(3)=6	2
Highest; Non-Routine.	Utilities.....	(4)×(2)=8	3

The degree of concordance between relative EVs and SMRs for all lymphohematopoietic cancer indicates that an increase in BD exposure, approximated by job category, is producing a real increase in SMRs for All LHC. (See Table 12).

TABLE 12.—THREE PAIRS OF VARIABLES

[EV's and associated SMRs for all lymphohematopoietic cancer]

Relative EV	Job group	EV	SMR
1	Maintenance	1	75
2	Production	6	146
3	Utilities	8	203

The results from Matanoski's recent nested case-control study of workers in this cohort (Ex. 29–1) indicated that BD is associated with the risk of developing leukemia. The leukemia risk may be seven to nine fold higher in workers with BD exposure versus those without such exposure. IISRP (Ex. 23–68) criticized this case-control study stating that the result is inconsistent with previous research. Matanoski's previous study of the same population found significant excess in mortality rates from leukemia among non-white production workers.

However, it is well established that case-control studies, as opposed to cohort studies, are proper for use in testing etiologic hypotheses for specific rare diseases (Ex. 23–69), and OSHA is of the opinion that this nested case-control study provides further evidence that exposures to BD are associated with an increased risk of death from cancer of the lymphohematopoietic system. OSHA is in the process of reviewing this study and the IISRP critique (Ex 29–1). They have been placed in the OSHA BD docket and are available for public review and comment.

The third study of SBR workers was conducted by McMichael et al. who studied the mortality experience of a cohort of 6,678 hourly male workers employed in a rubber tire manufacturing plant in Akron, Ohio between 1964 and 1972. During the 9-year follow-up period, 1,783 workers died. The Standardized Mortality Ratio (SMR) for all causes of death for the total cohort was 99.

McMichael observed statistically significant excesses of mortality due to cancers of the stomach (SMR=187, observed=39, expected=20.9, p less than 0.001), prostate, (SMR=142, observed=49, expected=34.4 p less than 0.05), and LSC (SMR=226, observed=14, expected=6.2, p less than 0.01) among the total cohort.

In a follow-up case-control study published in 1976, McMichael et al., (Ex. 23–4) evaluated the relationship of the mortality excesses to specific jobs within this plant. Complete work histories of 1,482 of the 6,678 workers were obtained and were separated into 16 job titles. One of these job-title categories included workers who were engaged in SBR manufacturing where there was a potential for exposure to BD.

Cases included all 339 individuals who had died from stomach, colorectal, respiratory, prostate, and bladder cancers, and all LHC. Their work histories were compared with those from workers in an age-stratified randomized control group selected from the remainder of the plant. The length of time cases and controls worked in the 16 occupational title groups (OTGs) was calculated in order to determine the "ratios-of-exposure rates" (RERs) among cancer cases compared to the rates among controls. The RER unit was used by both IARC (Ex. 21–31) and EPA (Ex. 17–27) to review the McMichael study (Ex. 23–4). An RER is obtained by dividing the percent of workers with cancer (cases) who worked in the synthetic plant for 2 or 5 years by the percent of workers without these cancers (controls) in the same work area by duration of exposure. If there is no association between work in an OTG and occurrence of a specific cancer, it is expected that the RERs will stay the same as length of time increases, such as occurred with colorectal and bladder cancer cases in the synthetic plant for 2 and 5 years. When the RERs increase with length of time, such as occurred for cancer of the stomach (1.7 for 2 years; 2.1 for 5 years), lymphatic leukemia (2.9; 3.7) and for all LHC (4.4; 5.6), a larger proportion of those who died from cancer worked for longer periods of time in the synthetic plant than expected, and the cancer is more likely to be associated with employment exposures to BD.

In reviewing these data, EPA (Ex. 17–27) stated that the increases in RERs for these neoplasms possibly indicated a dose-response relationship between exposure and cancer, thus strengthening the weight of evidence for causality. IARC (Exs. 23–31 and 23–32), relying on McMichael's finding that the age-adjusted RERs were 4.4 for those exposed for more than two years and 5.6 for those exposed more than 5 years, concluded that the study suggests an association between all lymphohematopoietic cancer (all LHC) and employment in SBR workplaces.

ICF (Ex. 23–19) pointed out that the major significance of the McMichael et al. study is to raise the index of suspicion concerning the role of SBR workplace exposures in contributing to the excess mortality among rubber workers, despite the failure, common in studies of chronic diseases, to match cases for age, race, and date of hire. OSHA's preliminary analysis agrees with this interpretation of the study. McMichael's age-stratified randomized sample of the total population, selected as controls, reduced the bias due to age.

(iii) *Workers Engaged in SBR Production and Fabrication of Rubber Products.* The cancer mortality experience of workers engaged in the general rubber industry, where workers are employed in SBR production, was investigated to separate excesses in mortality that are common to all general/SBR workers from site-specific cancer among SBR workers and, more specifically, from the mortality experience among those exposed to BD. A review of one study of general/SBR workers follows. One other study of general rubber workers (Monson, Exs. 23–5 and 23–6) was not included since the mortality experience of SBR workers was not studied separately.

Andjelkovic et al. 1976 studied the mortality experience, from January 1, 1964 through December 31, 1973, of 8,938 male rubber workers who worked any length of time in another rubber manufacturing plant located in Akron, Ohio. Some of the individuals worked in an SBR manufacturing area where there was a potential for exposure to BD.

During the 10-year observation period 2,373 (28%) of the white males died. Among all the workers, significantly elevated rates of death (p less than 0.05) due to monocytic leukemia (SMR = 311, Obs = 3) and "other LHC" were observed (SMR = 192, Obs = 10). This latter group included ICDA.-8 Revision, Nos. 202 (other), 208 (PV), 209 (MF).

Some have commented that studies of general/SBR workers are limited for use in evaluating the health effects of BD because workers experienced multiple exposures and the number of workers employed in the SBR departments of these plants was small. OSHA is of the opinion that the study results by Andjelkovic are consistent with the study results of Matanoski who found excess LHC and LSC/RCS among production workers exposed to SBR and BD monomer. Andjelkovic's study results are consistent with the results of McMichael who studied SBR workers and who demonstrated a dose-response relationship between employment in an OTG, where the major exposure was to BD, and "All LHC" and lymphatic leukemia. Patterns of similar site-specific cancer risks across studies of general/SBR workers and SBR workers and BD monomer production workers lend support to BD being associated with these cancers.

(iv) *Summary of the Epidemiologic Studies*—(a) *All Lymphohematopoietic Cancer (All LHC).* Tables 13 through 16 summarize the findings from each study with regard to all LHC. The rates of death generated in these five studies cover 45 years spanning two editions of the International Classification of Diseases (ICD), the seventh and the eighth revisions (Ex. 23-34). This long time span required achieving comparability between time periods covered when different rules of classification of underlying cause of death were in effect. Comparability codes for translation between the 7th and 8th revision of the ICD, developed by NCHS, (Ex. 23-44), were used to avoid artificially increased rates of death created by attributing deaths to a site-specific cancer solely because of a change in classification rules. There were no appreciable differences in the comparability statistics for leukemia. The comparability ratio is 0.9974, which indicated that the same number of deaths was assigned to "leukemia" whether the 7th or 8th revision was used (NCHS, 1975, Ex. 23-44).

For some cancer sites, no absolute equivalence can ever be achieved. For example, polycythemia vera (PV) and myelofibrosis (MF) were only classified as cancers in the 8th revision. At the level of aggregation used in these studies, this should present few problems since whatever effects occur should be controlled by using rates of death for the same causes-of-death in both the numerator and denominator of the SMRs. About five percent more deaths were assigned by the 8th revision to the group of neoplasms categorized as "other neoplasms of lymphatic and hematopoietic tissues" (ICDA.-8 Nos. 200-203, 208, 209) than were assigned by the 7th revision to the comparable title "Lymphosarcoma and other neoplasms of lymphatic and hematopoietic tissues" (ICD Nos. 200-203, 205). This increase was due in large part to the assignment of deaths to ICDA.-8, Nos. 200-203, 208, 209 by the 8th revision that were assigned ICD. Nos. 294, 295, 297-299 by the 7th revision. Most of these differences in assignments resulted from the transfer of PV to ICDA.-8 No. 208, in the eighth revision. In all the studies except Meinhardt's, which used the 7th revision, the 8th revision of the ICD was used. Potential problems relating to coding inequivalencies that remain should be limited to comparisons between "other LHC" in Meinhardt's study and "other LHC" in the other four studies. There are no coding differences between the McMichael, Matanoski, Downs, and Andjelkovic study results. Table 13 presents SMRs for All LHC for the five studies.

TABLE 13.—STANDARDIZED MORTALITY RATIOS (SMRs) AND OBSERVED DEATHS FOR ALL LYMPHOHEMATOPOIETIC CANCERS BY STUDY

Author (year)	SMR	Observed deaths	Cohort
Andjelkovic ('76)	124	52	Total (general/SBR).
McMichael ('74)	NR	NR	Total (general/SBR).
McMichael ('76)	[a]620	NR[a]	Synthetic latex department (SBR).
Meinhardt ('82)	155	9	Total Plant A (SBR).
Meinhardt ('82)	*212	9	War Plant A (SBR).
Matanoski ('87)[b]	097	55	Total (SBR).
Matanoski ('87)	146	19	Total production workers (SBR).
Matanoski ('87)	110	13	White production workers (SBR).
Matanoski ('87)	**504	6	Black production workers (SBR).
Downs ('86)	143	21	Total (BD).
Downs ('86)	187	6	Routine production workers (BD).

[a] This is a relative risk from a case/control study of 6.2 which is similar to an SMR of 620.
[b] These data come from the three-year update.
NR: Not Reported.
* p less than 0.05, one sided test.
** p less than 0.025, one sided test.

(b) *Leukemia.* Table 14 shows mortality from leukemia among BD exposed workers. Leukemia death rates were significantly elevated for black production workers in Matanoski's study (SMR=710, Obs=3, Exp=0.4). SMRs for leukemia were significantly elevated for "war-cohort" workers in Meinhardt's study (SMR=278, Obs=5). McMichael observed an increase in the relative risk of lymphatic leukemia for workers in the synthetic latex department where BD exposures occurred. Andjelkovic observed an elevated SMR for leukemia (SMR=138, Obs=25), and elevated SMRs for lymphatic leukemia and monocytic leukemia among workers in the total cohort, (SMR=152, Obs=10; SMR=311, Obs=3, $p<.05$, respectively). Downs reported an elevated SMR for leukemia among workers in the total cohort (SMR=119, Obs=7).

TABLE 14.—STANDARDIZED MORTALITY RATIOS (SMRs) AND OBSERVED DEATHS FOR LEUKEMIA BY STUDY

Author (year)	SMR	Observed deaths	Cohort
Andjelkovic ('76)	138	25	Total (general/SBR).
McMichael ('74)	128	16	Total (general/SBR).
McMichael ('76) (lymphatic only)	*390	NR	Synthetic latex department (SBR).
Meinhardt ('82)	203	5	Total Plant A (SBR).
Meinhardt ('82)	278	5	War Plant A (SBR).
Matanoski ('87)[b]	102	22	Total (SBR).
Matanoski ('87)	142	7	Total production workers (SBR).
Matanoski ('87)	89	4	White production workers (SBR).
Matanoski ('87)	**710	3	Black production workers (SBR).
Downs ('86)	119	7	Total (BD).
Downs ('86)	81	1	Routine production workers (BD).

* This is a relative risk of 3.9 from a case-control study which is similar to an SMR of 390.
[b] These data come from the three-year update.
NR: Not Reported.
* p less than 0.05, one sided test.
** p less than 0.025, one sided test.

In the McMichael, Andjelkovic, Matanoski, and Downs studies (ICD–8) and in the Meinhardt study (ICD–7), the diseases classified as leukemia are consistent.

(c) *Lymphosarcoma/Reticulum Cell Sarcoma (LSC/RCS).* Table 15 shows mortality due to lymphosarcoma and reticulum cell sarcoma (LSC/RCS). Significantly elevated excess death rates from LSC/RCS were observed by Downs (SMR=235, Obs=8), among the total cohort of BD workers. Meinhardt observed elevated death rates for these cancers (SMR=224, Obs=3) among "war-cohort" workers. Matanoski however, did not observe an excess SMR for these cancers in total production workers. In all these studies, whether ICD–7 or ICD–8 is used, the classification of diseases in this category is consistent (includes only ICD–7, No.200 or ICDA–8, No. 200) except for routine workers as classified by Downs. For this group, ICDA. Nos. 200, 202, 203, 208, and 209 are included. Users of this data should be aware of the fact that this one group in Tables 11 and 12 includes more than just LSC/RCS cancers coded as ICDA. No. 200. The numbers of expected and observed cancers in some study subgroups are small.

TABLE 15.—STANDARDIZED MORTALITY RATIOS (SMRs) AND OBSERVED DEATHS FOR LYMPHOSARCOMA/RETICULUM CELL SARCOMA BY STUDY

Author (year)	SMR	Observed deaths	Cohort
Andjelkovic ('76)	088	8	Total (general/SBR).
McMichael ('74)	**226	14	Total (general/SBR).
McMichael ('76)	NR	NR	Synthetic latex department (SBR).
Meinhardt ('82)	181	3	Total Plant A (SBR).
Meinhardt ('82)	224	3	War Plant A (SBR).
Matanoski ('87)	*061	7	Total (SBR).
Matanoski ('87)	038	1	Total production workers (SBR).
Matanoski ('87)	0	0	White production workers (SBR).
Matanoski ('87)	530	1	Black production workers (SBR).
Downs ('86)	*235	8	Total (BD).
Downs ('86) [b]	282	4	Routine production workers (BD).

* These data come from the three year update.
[b] Includes ICD–7 Nos. 200 (LSC/RCS), 202 (Other), 203 (MMY), 208 (PV), and 209 (MF).
NR: Not Reported.
*p less than 0.05 two-sided test.
**p less than 0.01 two-sided test.

(d) *Other LHC.* As shown in Table 16, Matanoski observed a significant excess of "other LHC" (ICDA.–8, "other", MMY, PV) among all production workers (SMR=260, Obs=9). Andjelkovic reported a significant excess for "other LHC" [ICD–8, other, PV, and MF (SMR=192, Obs=10)] among the total cohort of workers. Downs reported an elevated SMR of 124 (Obs=4) for "other LHC" (ICD–8, other, MMY, and PV) among workers in the total cohort.

TABLE 16.—STANDARDIZED MORTALITY RATIOS AND OBSERVED DEATHS FOR OTHER CANCERS OF THE LYMPHOHEMATOPOIETIC SYSTEM BY STUDY

Author (year)	SMR	Observed deaths	Cohort
Andjelkovic ('76)	**192	10	Total (general/SBR).
McMichael ('74)	NR	NR	Total (general/SBR).
McMichael ('76)	NR	NR	Synthetic latex department (SBR).
Meinhardt ('82)	0	0	Total Plant A (SBR).
Meinhardt ('82)	0	0	War Plant A (SBR).

TABLE 16.—STANDARDIZED MORTALITY RATIOS AND OBSERVED DEATHS FOR OTHER CANCERS OF THE LYMPHOHEMATOPOIETIC SYSTEM BY STUDY—Continued

Author (year)	SMR	Observed deaths	Cohort
Matanoski ('87)[b]	111	17	Total (SBR).
Matanoski ('87)[b]	*260	9	Total production workers (SBR).
Matanoski ('87)[b]	230	7	White production workers (SBR).
Matanoski ('87)[b]	480	2	Black production workers (SBR).
Downs ('86)[b]	124	4	Total (BD).
Downs ('86)[c]	282	4	Routine production workers (BD).

NR Not reported.
* p less than 0.05 two-sided test.
[a] Includes: other lymphoma, polycythemia vera, myelofibrosis.
[b] ICDA.–8 Nos. not given for the category "other".
[c] Includes: MMY, LSC/RCS, other, NHL, PV, and MF.

(v) *Summary.* The observation of a qualitative dose-response between BD and lymphohematopoietic cancer (LHC), with data from the Downs and Matanoski studies, may not exclude the possibility that other exposures in the plants were associated with elevated SMRs for LHC. Since the dose-response relationship exists between LHC and BD, these other exposures would have to be associated with and parallel to BD exposures in order to be associated with increases in LHC. That is, these other exposures would have to increase and decrease over time in the same way that BD exposures changed. Since exposures to other substances would differ between SBR and BD production workplaces, the presence of other exposures is less likely to explain the dose-response for BD production workers where exposures are primarily due to BD. Thus, it is OSHA's opinion that BD exposure is the most likely factor associated with the qualitative dose-response relationship in these two studies.

Results from three other epidemiologic studies evaluated by OSHA are consistent with the results from Downs and Matanoski. A dose-response relationship was demonstrated for BD exposure and LHC and leukemia in the McMichael study, using ratio-of-exposure-rates. In the Meinhardt study, SMRs for all LHC and leukemia were significantly elevated among workers who had the highest relative exposures, in terms of process changes (hot batch versus cold process). This, plus the observation of elevated SMRs for leukemia and other LHC cancer in Andjelkovic's study, is consistent with the study results of Downs, Matanoski, and McMichael.

On the basis of the consistency of results from the five epidemiologic studies evaluated, OSHA is of the opinion that exposure to BD is associated with an increased risk of death from cancer of the lymphohematopoietic system. The epidemiologic findings supplement the findings from the animal studies that demonstrate a dose-response for multiple tumors and particularly for lymphomas in mice exposed to BD.

C. Reproductive Effects

Although there are no data on the potential reproductive or developmental effects of BD exposure in humans, there are several relevant studies in animals. The earliest study, conducted by Carpenter *et al.* (Ex. 23–64) in 1944, found evidence of maternal toxicity in rats consisting of decreased litter size when the rats were exposed to BD at 2,300 or 6,700 ppm. No effects were reported when exposures were 600 ppm. This limited information is now augmented by several recent studies conducted in rats and mice.

In 1981, the IISRP sponsored a study of the teratogenic effects of BD in Sprague-Dawley rats (Ex. 2–32). In this study, conducted by Hazleton Laboratories Europe Ltd., groups of 24 pregnant rats were exposed to BD for 6 hours/day at airborne concentrations of 200 ppm, 1,000 ppm, or 8,000 ppm on days 6 through 15 of gestation. Negative controls consisted of 40 pregnant rats maintained in filtered air; positive controls were exposed to acetylsalicylic acid by gavage. The mated rats were killed by cervical dislocation on day 20 of gestation, dissected, and examined macroscopically. Live fetuses were killed by intracardiac injection of pentabarbitone sodium solution. Each fetus was weighed, measured and its exterior was examined. Two-thirds were dissected and the viscera examined; tissue was cleared and the skeletons examined for abnormalities. The remaining fetuses were sectioned and examined for abnormalities.

There was a dose-related effect of BD exposure on maternal body weight gain with an actual loss of weight in the first few days. Postimplantation loss was slightly higher in all BD-exposed groups. There was also a dose-response effect of BD exposure on mean fetal weight and crown-to-rump length. Post implantation losses and growth retardation were thought by the author to be related to the reductions in body weight gain experienced by the dams.

The incidence of minor external and visceral defects was higher in the litters exposed to BD than in the negative control animals. Significant increases in hematoma incidence occurred in the fetuses in the 200 and 1,000 ppm groups; the 8,000 ppm group had a significantly increased number of fetuses with lens opacities. Two fetuses in the 8,000 ppm group had rare or life-threatening cardiovascular abnormalities and one also showed abnormal facial shape, subcutaneous edema, sunken eyes, and undescended testicles.

The incidence of litters with fetuses showing skeletal variants was significantly higher than controls in the 8,000 ppm group. There was also a significantly higher incidence of bipartite thoracic centra in all BD-exposed groups and a significantly elevated incidence of incomplete ossification of the sternum in the highest exposure group compared to negative control animals. This 8,000 ppm group also had a significantly higher incidence of irregular ossification of the ribs. BD-exposed fetuses had a higher incidence of life-threatening or rare skeletal defects. The majority of these major skeletal defects were wavy ribs, and the incidence of fetuses with wavy ribs was statistically higher than in controls in the 8,000 ppm group. This group also exhibited other major skeletal defects including abnormalities of the skull, spine, long bones, and ribs.

The author concluded that any evidence of teratogenicity at the two lower doses was equivocal; the effects could also be attributed to a combination of maternal toxicities and differences in behavior of this group of

animals from historical controls. The authors concluded, however:

> At the highest dosage, even discounting the wavy ribs, there was still a higher incidence of major foetal defects than in the control group. This, therefore, should be regarded as an effect of BD exposure at 8,000 ppm v/v on embryonic development.

At the "International Symposium on the Toxicology, Carcinogenesis, and Human Health Aspects of 1,3-Butadiene," held at Research Triangle Park, North Carolina, on April 12–13, 1988, Morrissey described the results of research on reproductive and developmental toxicity studies of BD in rodents (Ex. 23–71). (See also Exs. 23–72, 23–73, 23–74, 23–75). Pregnant Sprague-Dawley rats (24–28 per group) and Swiss (CD–1) mice (18 to 22 per group) were exposed to BD 6 hours/day at 0 ppm, 40 ppm, 200 ppm, or 1,000 ppm from days 6 through 15 of gestation. The animals were weighed and observed for signs of toxicity. One day before expected delivery, they were killed and the numbers of implantation sites, resorptions, and live and dead fetuses were tabulated. Fetuses were weighed and subjected to external, visceral, and skeletal examinations (Exs. 23–71, 23–72, 23–73).

In the rats, there was evidence of maternal toxicity only in the 1,000 ppm group; i.e. depressed body weight gains during the first 5 days of exposure. The percentage of pregnant animals and the number of litters with live fetuses were unaffected by treatment. Placental weights, fetal body weights, and sex ratios were unaffected by treatment. There were no significant differences among groups in incidence of fetal malformations. The investigators concluded that "under the conditions of this exposure regimen, there was no evidence for a teratogenic response to BD exposure" (Ex. 23–73, p. vi).

In mice, significant concentration-related decreases were detected in weight gains during the last 5 days of exposure and from the end of exposure to sacrifice, body weight at sacrifice, extragestational weight and weight gain, and weight of the gravid uterus. There was a significant concentration-related depression of fetal body weights and placental weights.

Body weights of male fetuses were significantly lower than those of control fetuses at all concentrations; in the female mice, significant depression of weights occurred only at 200 and 1,000 ppm. Weights of placentas of male fetuses were significantly decreased in the 200 ppm and 1,000 ppm exposure group; placentas of female fetuses were affected significantly only at 1,000 ppm. There were no significant differences among groups in the incidences of malformations. However, incidences of supernumerary ribs and reduced ossification were significantly increased in litters of mice exposed to BD at 200 and 1,000 ppm.

This exposure regimen clearly produced signs of maternal toxicity in mice exposed at 200 ppm and 1,000 ppm. Fetal growth retardation and increased incidences of morphologic variations were also observed to occur in a concentration-related manner. These results indicated to the authors "that the fetus [may] be more susceptible than the dam" (Ex. 23–72, p. vi), but "no evidence of teratogenicity was found."

To examine the effects of inhalation of BD on the reproductive system, the investigators conducted sperm head morphology tests with $B6C3F_1$ mice and a dominant lethal study using Swiss (CD–1) mice (Ex. 23–71). In both studies, groups of 20 mice were exposed to BD for 6 hours/day for 5 consecutive days at concentrations of 0 ppm, 200 ppm, 1,000 ppm, or 5,000 ppm.

In the sperm head morphology study, the mice were killed in the fifth postexposure week and examined for gross lesions of the reproductive tract (Ex. 23–75). Suspensions of the epididymal sperm were prepared for morphologic evaluation. Although signs of toxicity were mild and transient and occurred only in the highest exposure group, there was a concentration-related increase in the incidence of sperm head abnormalities. The percentage of sperm heads morphologically abnormal was significantly increased in the mice exposed at 1,000 and 5,000 ppm. Since the assay was conducted only during the fifth post-exposure week, it was not designed to detect effects at all stages of gamete development, leading the authors to conclude that "at least the late spermatogonia or early primary spermatocytes may be sensitive to alteration by exposures of mice to 1,000 ppm or higher concentrations of BD" (Ex. 23–75, p. v).

In the study of dominant lethality, male CD–1 mice were exposed to BD at 0 ppm, 200 ppm, 1,000 ppm, and 5,000 ppm for 6 hours/day for 5 consecutive days (Ex. 23–74). Body weights and signs of toxicity were observed in the males throughout the study. The only evidence of toxicity was transient, occurring over a 20 to 30 minute period following exposure at 5,000 ppm.

Subsequent to exposure, each male was mated with two unexposed females for 1 week. Mating was continued for 8 weeks with replacement of the females each week. The females were killed 12 days after their removal to evaluate their reproductive status. Gravid uteri were removed for determination of the number, position, and status of implantations.

Females mated to the BD-exposed males during the first 2 weeks post exposure were described as more likely than control animals to have increased numbers of dead implantations per pregnancy. The percentage of dead implantations in litters sired by males exposed at 1,000 ppm was significantly higher than controls for weeks 1 and 2; the numbers of dead implantations per pregnancy in litters sired by males exposed at 200 ppm and mated during the second post exposure week were also significantly increased. The percentage of females with two or more dead implantations was significantly higher than the control value for the first mating for all three exposure groups. These results suggested to the authors that the more mature cells (spermatozoa and spermatids) may be altered by exposure to BD (Ex. 23–74).

In the first NTP bioassay, previously described, $B6C3F_1$ mice were exposed to BD for 60 or 61 weeks. An increased incidence of testicular atrophy was observed in the males (none in controls, 40% in the 625 ppm group, 20% at 1,250 ppm). Female mice had an increased incidence of ovarian atrophy and uterine involution (2/49 in controls, 40/45 at 625 ppm, and 40/48 at 1,250 ppm and 0/40 in controls, 7/46 at 625 ppm, and 14/49 at 1,250 ppm, respectively).

These results are being confirmed in the second NTP study which was described by Melnick *et al.* (Ex. 23–59). After 65 weeks of a study intended to continue a full two years, $B6C3F_1$ mice exposed to BD at 0, 6.25, 20, 62.5, 200, or 625 ppm for 6 hours/day, 5 days/week demonstrated an increased incidence of testicular atrophy at 625 ppm and ovarian atrophy at all doses of 20 ppm or greater. The animals examined consisted of those sacrificed at 40 and 60 weeks and those that had already died, either from BD-related causes, mainly lymphocytic lymphoma, or from unrelated causes.

The cancer bioassays provided other indicators that chronic inhalation of BD alters the reproductive system (Ex. 23–71). In the rat study, described previously, there was an increased incidence of a number of tumors of the reproductive tract, including Leydig cell tumors of the testes and uterine/vaginal stromal tumors. The NTP-sponsored study, in which mice were exposed to BD at 625 ppm and 1,250 ppm, was terminated early because of high mortality associated with neoplasms at

multiple sites, including ovarian granulosa cell tumors.

In its Current Intelligence Bulletin, NIOSH concluded (Ex. 22–17):

> * * * there is a possible reproductive hazard to workers exposed to BD based on maternal and fetal toxicity observed in BD exposed rats; an indication of teratogenicity in exposed rats, and suggestion of testicular and ovarian atrophy in mice exposed to BD.

OSHA agrees with these conclusions; in fact, evidence from sperm morphology tests and dominant lethal assays coupled with confirmation of the results of the first NTP study of the carcinogenicity of BD strengthen these conclusions. The effects appear in the male and the female rodents as well as in the fetus. Indeed, the lowest concentration presently known to produce an effect in the adult rodent is 20 ppm. In contrast, no evidence of any teratogenic effects has been seen at concentrations below 8,000 ppm, even though two species have been tested. Thus, the adult rodent's reproductive functioning may be at much greater risk than in utero risks to the fetus.

D. Other Relevant Biological Data

Additional information that assisted OSHA in developing a standard for BD is presented below, including acute hazards and summaries of studies of the distribution and metabolism of BD, the genotoxic effects of BD, the genotoxic and carcinogenic effects of BD metabolites and their structural analogues, and other data indicating that BD can influence hematologic parameters, either directly or as a consequence of its toxicity to the bone marrow.

1. Acute Hazards

To determine if a chemical has effects that pose an acute health hazard, as a minimum, OSHA examines irritation, corrosivity, sensitization, and lethal dose.

At very high concentrations, BD produces narcosis with central nervous system depression and respiratory paralysis (Ex. 2–11). LC_{50} values (the concentration that produces death in 50 percent of the animals exposed) were reported to be 122,170 ppm (12.2% v/v) in mice exposed for 2 hours and 129,000 ppm (12.9% v/v) in rats exposed for 4 hours (Exs. 2–11, 23–91). These concentrations would present an explosion hazard, thus limiting the likelihood that humans would risk any such exposure except in an extreme emergency. Oral LD_{50} values (oral dose that results in death of 50 percent of the animals) of 5.5 g/kg body weight for rats and 3.2 g/kg body weight for mice have been reported (Ex. 23–31). These lethal effects occur at such high doses that BD would not be considered "toxic" for purposes of Appendix A of OSHA's Hazard Communication Standard (29 CFR 1910.1200) which describes a classification scheme for acute toxicity based on lethality data.

At concentrations slightly above the existing standard of 1,000 ppm, BD is a sensory irritant. Concentrations of several thousand parts per million were reported to cause irritation to the skin, eyes, nose, and throat (Exs. 23–64, 23–94). Two human subjects exposed to BD for 8 hours at 8,000 ppm reported eye irritation, blurred vision, coughing and drowsiness (Ex. 23–64).

2. Systemic Effects

Identification of the tissues and organ systems that may be adversely affected by exposure to a toxic chemical is important for two reasons: (1) The effects resulting from the systemic toxicity may be sufficiently severe that they must be prevented to protect worker health, and (2) the target organs and doses identified in subacute and subchronic range finding tests provide important information for the design of cancer bioassays. The section below explores the information available that indicates potential target organs for BD.

As noted by IARC (1986) in that agency's review of the toxicity of BD (Ex. 23–31), several studies from the U.S.S.R. have ascribed various adverse effects to occupational exposure to BD. The effects reported include hematologic disorders, liver enlargement and liver and bile-duct diseases, kidney malfunctions, laryngotracheitis, upper respiratory tract irritation, conjunctivitis, gastritis, various skin disorders and a variety of neuraesthenic symptoms. Few are substantiated by details on the atmospheric concentration or duration of exposure, and control data were not generally provided (Ex. 23–31), greatly limiting the usefulness of the studies for standards-setting purposes. Except for sensory irritant effects and hematologic changes, evidence from studies of U.S. workers do not corroborate the Russian studies. In animal studies, described below, the kidney and liver were affected by BD, but only at doses that also produced a large number of cancers.

For example, Hazleton Laboratories performed a 3-month subchronic study of BD exposure in Sprague Dawley rats (Ex. 2–11). Five groups of rats were exposed to BD at concentrations of 0, 1,000, 2,000, 4,000 and 8,000 ppm 6 hr/day, 5 days/week for 13 weeks. Forty male and forty female animals were included in each group, with 10 of each sex being killed at weeks 2 and 6 of the study. The authors reported that "no untoward effects attributable to exposure were observed, except a moderately increased salivation * * * at higher concentrations of butadiene" (Ex. 2–11). The authors also found no treatment-related changes in growth rate, food consumption, hematological and blood biochemical parameters, or from urine analysis. There was no evidence of macroscopic or histhopathologic changes in the tissues or organs examined. An increase in erythrocyte cholinesterase activity in the exposed animals was not considered an adverse effect by the authors.

In addition to the subchronic study, the Hazelton Laboratory group examined the rats exposed to BD in their 2-year cancer bioassay (described earlier) for other signs of toxicity. Studies included: hematological analysis, tests of neuromuscular function, and histologic examination of post-mortem tissues and organs (Exs. 2–31, 23–84). The only finding in the hematological examination that the authors attributed to BD was higher leukocyte counts in the high dose (8,000 ppm) females during the first year; the authors did not consider this toxicologically significant. As the experiment progressed, BD-exposed animals tended to be less able to remain on a rotating cone, test results which might indicate an adverse change in neuromuscular function. However, the results may have been influenced by the presence of mammary masses which made the test more difficult for affected animals to complete.

Kidney weight was increased in the high dose males, and the authors reported that kidney damage was the major cause of an increased death rate observed during the second year of the experiment. Liver weights at both doses (1,000 and 8,000 ppm) were increased, but associated pathological changes were not found upon microscopic examination of the tissue. As noted by the EPA (Ex. 17–21, p. 3–3), this could be indicative of BD-induced liver enzyme changes.

In the NTP bioassay, $B6C3F_1$ mice exposed to BD at 625 or 1,250 ppm 6 hr/day, 5 days/week for 61 weeks (see section on carcinogenicity) showed atropy of the ovary and testes, atropy and metaplasia of the nasal and respiratory epithelium, hyperplasia of the forestomach epithelium, and liver necrosis (Exs. 23–1, 23–92). The nasal cavity changes are of interest since an epoxide, 1,2-epoxybutane, with a structure closely related to a BD metabolite, epoxybutene, caused similar

changes when tested by inhalation in another NTP bioassay (Ex. 23–85).

3. Bone Marrow Toxicity

Epidemiologic studies of the styrene-butadiene rubber (SBR) industry suggest that workers exposed to BD are at increased risk of developing leukemia or lymphoma, two forms of hematologic malignancy (see section on epidemiology). Consequently, investigators have looked for evidence of hematopoietic toxicity resulting from BD exposure in animals and in workers. For example, Irons *et al.* of CIIT found that exposure of male $B6C3F_1$ mice to 1,250 ppm of BD for 6–24 weeks resulted in macrocytic-megaloblastic anemia, an increase in erythrocyte micronuclei and leukopenia, principally due to neutropenia. Bone marrow cell types overall were not altered, but there was an increase in the number of cells in the bone marrow of exposed mice due to an increase in DNA synthesis (Ex. 23–12).

Melnick *et al.* (Ex. 23–59) of the NTP are exposing $B6C3F_1$ mice to BD for 6 hours/day, 5 days/week at concentrations of 0, 6.25, 20, 62.5, 200, and 625 ppm in an ongoing study of the carcinogenic effects of BD. These investigators simultaneously are looking for evidence of effects on the reticuloendothelial system. Interim sacrifices conducted at 40 and 60 weeks into the investigation, for example, included examination of hematologic parameters. Exposure to BD, so far, has caused a poorly regenerative anemia at concentrations of 62.5 ppm or above.

The results from the Melnick study are confirmed and extended by a series of studies conducted by Irons and co-workers at the CIIT. For example, Irons (Ex. 23–59) observed that chronic exposure of $B6C3F_1$ mice to 1,250 ppm of BD, 6 hours/day, 5 days/week for 12 or 52 weeks resulted in a 21 percent and 57 percent incidence of thymic lymphoma/leukemia, respectively. Leukemogenesis was preceded by anemia and bone marrow cytogenetic abnormalities. NIH Swiss mice were also exposed to BD for 52 weeks, and 14 percent of these animals developed thymic lymphoma/leukemia; hematologic and cytogenetic abnormalities were reported as being "indistinguishable from those encountered in $B6C3F_1$ mice".

Alterations in hematopoietic stem cells in the bone marrow of $B6C3F_1$ mice exposed to BD have also been seen in the CIIT studies. Assays of long-term bone marrow cultures of exposed mice showed decreased granulocyte macrophage precursor cells after 14 days but increases in numbers after 28 days, indicative of a shift in maturation or delay in differentiation (Ex. 23–13).

Based primarily on the studies of mice, the bone marrow appears to be one of the targets of BD toxicity. The mechanism of toxicity is not certain but Irons has hypothesized that it may be interference with normal bone marrow cell differentiation and/or DNA synthesis (Ex. 23–12).

The results in humans exposed to BD in the course of their work are consistent with the evidence in mice, but unlike the animal studies, the human evidence is insufficient to definitively conclude that there is bone marrow toxicity demonstrated from BD exposure. Checkoway and Williams (Ex. 2–28) examined 163 hourly production workers who were employed at the SBR facility studied by McMichael *et al.* (Ex. 23–4). At the time of the Checkoway and Williams survey, the plant was manufacturing hot and cold styrene-butadiene rubber and, to a lesser extent, vinyl pyridine latex and carboxylated rubber.

Questionnaires eliciting medical histories of acute and chronic infections, malignant disease, anemia, allergies, vaccinations, radiation, and medication use were administered and blood samples were drawn. One of the 163 men reported a history of leukemia, and he was excluded from further study.

Exposure to BD, styrene, benzene, and toluene was measured in all areas of the plant. BD and styrene concentrations, 20 (0.5–65) ppm and 13.7 (0.14–53) ppm, respectively, were considerably higher in the Tank Farm than in other departments. In contrast, benzene exposures, averaging 0.03 ppm, and toluene concentrations, averaging 0.53 ppm, were low in the Tank Farm. Consequently, the authors compared the hematologic profiles of Tank Farm workers (n=8) with those of the other workers examined.

The investigation focused on two potential effects, bone marrow depression and cellular immaturity. Bone marrow depression was suspected if there were lower levels of erythrocytes, hemoglobin, neutrophils, and platelets. Cellular immaturity was suggested by increases in reticulocyte and neutrophil band form values.

Although the differences were small, hematologic parameters, adjusted for age and medical status, in the Tank Farm workers differed from those of the other workers. Except for total leukocyte count, the hematologic profiles of the Tank Farm workers were consistent with an indication of bone marrow depression. The Tank Farm workers also had increases in band neutrophiles, a possible sign of cellular immaturity, but no evidence that increased destruction of reticulocytes was the cause.

While admitting the limitations of the cross-sectional design of the study, the authors felt, nevertheless, that their results were "suggestive of possible biological effects, the ultimate clinical consequences of which are not readily apparent." OSHA finds any evidence of hematological changes in workers exposed at BD levels well below the existing permissible limit of 1,000 ppm to be of interest since such information suggests the inadequacy of the PEL. However, the study involves only 8 workers with relatively high levels of exposure to BD and low levels of exposure to benzene, so it is quite insensitive to minor changes in hematologic parameters.

In a review of BD published in 1986 by IARC, the Working Group felt the study of Checkoway and Williams could not be considered indicative of an effect of BD on the bone marrow (Ex. 2–28). In light of the more recent animal studies that were not available to IARC, however, OSHA believes that the bone marrow is a target of BD toxicity. Furthermore, the fact that changes in hematologic parameters could be distinguished in workers exposed to BD at 20 ppm indicates that such measurements are a sensitive indicator of excessive exposure to BD.

Some investigators believe that lymphomas in mice are of a viral origin, and they question the relevance of mouse lymphoma to human cancer (Ex. 23–70, p. 55). Two separate strains of mice, however, have developed lymphoma/leukemia following BD exposure, and the cancers were preceded by hematologic and cytogenetic abnormalities. Hematologic changes are also characteristic in cases of human leukemia, although lymphoma may not provide such an indicator. The extent to which hematologic changes in humans exposed to BD may be associated with leukemia is not known. However, the combined information in mice and humans suggests that changes in hematologic parameters should be considered a toxic endpoint that can result from BD exposure.

4. Metabolism

According to the classical electrophilic theory of carcinogenesis developed by Miller and Miller, organic chemicals require metabolic activation to exert their cancer-inducing properties. Although the original molecule is relatively or completely inactive, various metabolites have greater carcinogenic activity; these metabolites are termed the proximate and ultimate

carcinogens. Ultimate carcinogens are electrophilic (electron deficient) reactants that bind with target intracellular nucleophilic (electron-rich) macromolecules such as DNA and proteins. The enzymes usually involved in the biotransformation of a chemical to carcinogenically active metabolites, and the microsomal mixed function oxidases, are part of the same mechanism responsible for detoxification of drugs (Ex. 23–70, p. 12).

The reactive metabolites may also bind with other nucleophiles such as glutathione or water. Through these latter processes, the effects of agents can be neutralized by forming less biologically reactive metabolites that are very polar and more easily excreted. The efficiency of this neutralization is an important factor in tumor induction (Ex. 23–70, p. 12). As described below, BD's metabolic reactions fit this classical description of the activation and detoxification steps in carcinogenesis.

Although every organic carcinogen cannot be described by the electrophilic theory of carcinogenesis, evidence that a chemical, such as BD, has properties consistent with this theory adds to OSHA's confidence that the substance is properly classified as to its carcinogenic potential. Such evidence would include: the identification of reactive metabolites, information that these metabolites possess mutagenic or carcinogenic activity, information that close structural analogues possess similar genotoxic properties, and studies showing that identified metabolites are capable of binding to DNA. These topics are explored in the sections below beginning with information on metabolic pathways for BD and the implications for human health protection.

Based on the electrophilic theory of chemical carcinogenesis, scientists predict that certain structural units present in a molecule will make it likely that the molecule will be a carcinogen when tested in animals. Aliphatic and aromatic epoxides are one of these structural classes. As described below, several BD metabolites are aliphatic epoxides suggesting a mechanism of action to explain BD's carcinogenic activity.

In vitro studies indicate that BD is converted to epoxybutene (vinyl oxirane) by mixed function oxidases in rat liver microsomes. Pretreatment of rats with phenobarbital increases enzyme activity. Epoxybutene undergoes further conversion to 1,2:3,4-diepoxybutane and 3-butene-1,2 diol; the latter product is converted by mixed function oxidases to 3,4-epoxy-1,2-butanediol.

Because of their genotoxic properties (see section on mutagenicity), the two epoxides, epoxybutene and 1,2:3,4-diepoxybutane, which have been identified from *in vitro* studies, are suspected of being the ultimate carcinogens that account for the carcinogenic properties of BD. A metabolic pathway suggested for BD, based on *in vitro* studies, is presented in Figure 1.

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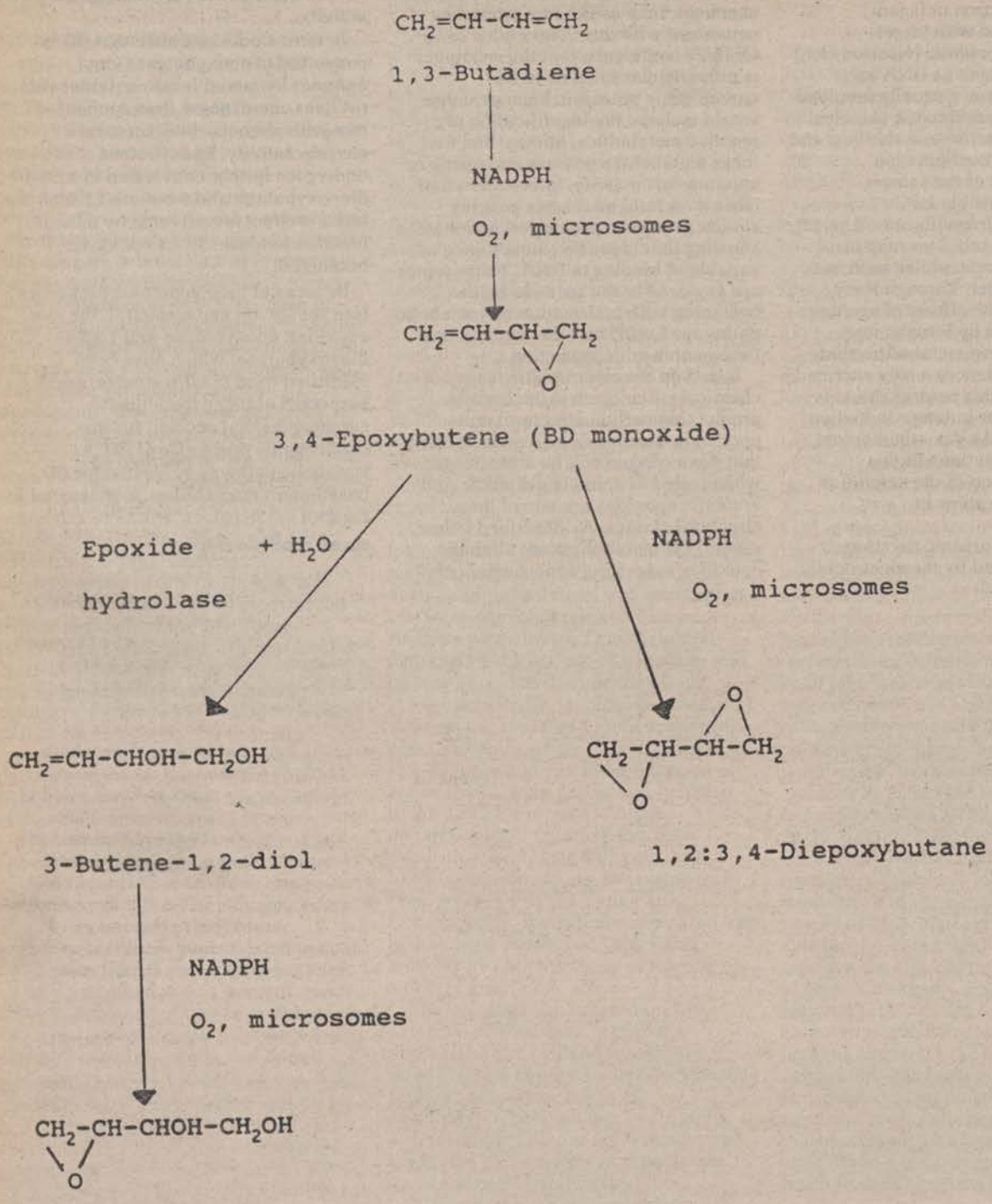

Figure 1. Possible Metabolic Pathway for BD (Ex.23-60).

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Epoxybutene also reacts both chemically and enzymatically with glutathione-S-transferase to form a glutathione conjugate (Malvoisin and Roberfroind, 1982). According to the EPA, the significance of this observation with respect to the toxicity of epoxybutene awaits further investigation (Ex. 17–21, p. 4–3). Generally, however, glutathione conjugation is a detoxification process that enhances the excretion of toxic chemicals.

Intact animals are also known to metabolize BD to epoxybutene. In the closed-chamber method, a fixed amount of test chemical is placed in the chamber, and the concentration of this chemical is measured over time. A decline in concentration indicates that there has been uptake and metabolism of the test chemical by the animal. Exhaled metabolites can also be identified using the closed chamber method (Ex. 17–21, pp. 4–4 to 4–8).

Using the closed-system technique, investigators led by Bolt (Exs. 23–95, 23–96) found that exposure of rats to BD at concentrations exceeding 1,000 ppm led to a constant accumulation of epoxybutene. When concentrations of BD were 1,000 ppm or less, the concentration of epoxybutene declined in approximately first-order fashion, suggesting that epoxybutene was reabsorbed and further metabolized.

Comparative studies on species differences in the disposition of inhaled BD have also been conducted by the closed chamber method and using nose-only exposure to constant atmospheric concentrations of BD. These studies were initiated to determine if there were differences in the uptake and distribution of inhaled BD between rats and mice that were consistent with the differences in species susceptibility to cancer developed as a result of BD exposure.

For example, Kreiling *et al.* (Ex. 23–98) conducted closed chamber experiments in $B6C3F_1$ mice. Comparing their results to those calculated for Sprague-Dawley rats by Bolt *et al.*, Kreiling *et al.* concluded that the rate of metabolism of BD in mice was approximately twice that in rats.

In a different type of test where the chamber concentration is held constant, Bond *et al.* (Ex. 23–86) exposed rats and mice to BD for 6 hours in a nose-only device. Concentrations were 0.14 μg/l (0.08 ppm) to 1,870 μg/l (842 ppm) for mice or 0.14 μg/l (0.08 ppm) to 12,700 μg/l (5,715 ppm) for rats. One group of 4 to 6 animals was killed at the end of exposure to determine the total amount of radioactivity retained in the body. A second group of four animals was retained in metabolism cages for up to 70 hours after exposure to determine radioactivity in urine, feces, and expired air. Rats and mice from the third group of nine animals were euthanized at various times throughout the exposure period to determine the presence of BD and its metabolites in blood.

The amount of ^{14}C retained at 6 hours ranged from 1.5 (5,715 ppm) to 17 percent (0.8 ppm) in rats and 4 (842 ppm) to 20 percent (6.4 ppm or less) in mice. There was a significant (p less than 0.001) concentration-related decrease in the percentage of inhaled BD retained with increasing exposure concentration for both rats and mice. When the total amount of ^{14}C retained at 6 hours was normalized to body weight or body surface area, mice accumulated a larger amount of radioactivity than rats exposed at the same concentration.

Urine and exhaled air were major routes of excretion of ^{14}C in both rats and mice. At low concentrations (6.4 ppm), all ^{14}C exhaled by mice was accounted for as metabolites; at 65 ppm and above, BD was also present. In rats, there was a shift in the main route of excretion from urine at 60 ppm to exhaled air at 5,715 ppm.

Overall, greater than 90 percent of the ^{14}C in the blood of the rats and mice consisted of BD metabolites, mostly nonvolatile materials. At 65 and 842 ppm, mice had nearly twice the concentrations of 1,2-epoxy-3-butene in the blood as rats exposed at similar concentrations.

It is of interest that any epoxide intermediates were found in the blood and exhaled air. This indicates that these reactive molecules are sufficiently stable to be available to interact with critical macromolecules.

The findings in this study suggest several reasons why species differences have been seen in the carcinogenicity studies. First, over a wide range (0.08 to 842 ppm), mice received a larger amount of inhaled BD per unit of body weight than rats. Second, mice had significantly higher concentrations of 1,2-epoxy-3-butene in the blood than rats; to the extent that this metabolite is the ultimate carcinogen, the mice would be at greater risk of developing cancer.

Bond *et al.* (Ex. 23–87) conducted further studies to determine if there were differences between rats and mice in the distribution of BD in tissues following inhalation exposure. Male Sprague Dawley rats were exposed to BD at 549 ppm and mice were exposed at 54 ppm. These concentrations were selected because they were known to result in retention of similar amounts of BD and metabolites.

Radioactivity was distributed widely in tissues immediately following exposure of both rats and mice. Blood concentrations of ^{14}C were low compared to other tissues in both rats and mice. In all cases, tissues of mice contained higher concentrations of ^{14}C per umole of BD inhaled than did rats; in most cases mouse tissue contained 15 to 100 times that of rat tissue. In rats, all tissues examined contained a substantial amount of nonvolatile BD metabolite. Similar results were found in mouse liver, the only mouse tissue available for analysis. This study indicated that: (1) BD or its metabolites is widely distributed in the tissues following exposure and the tissues of mice contain higher concentrations of these materials than rats. These findings are consistent with the evidence that BD can cause cancer at multiple sites in experimental animals.

The studies of the metabolism and distribution of BD provide a wealth of information consistent with a conclusion that BD should be regarded as an occupational carcinogen. In laboratory animals (and thus presumably in humans) BD is readily absorbed through inhalation and is distributed widely throughout the body (Ex. 17–21). To some extent, this widespread distribution would be necessary to account for the numerous sites where cancers were induced in animals. However, cancer is not induced at all of the sites where BD is retained. This finding is completely consistent with the electrophilic theory of carcinogenesis which would take the position that the parent compound, BD, is not the reactive chemical. According to this theory of carcinogenesis, cancer would occur only at the organ sites where the ultimate carcinogen, a reactive epoxide, is formed.

The finding that the mouse's target organs are exposed to a greater concentration of the reactive epoxides that probably are responsible for BD's carcinogenic activity also helps to explain apparent species differences in cancer incidence. (There are however, substantial differences between the protocols used in the studies of mice and rats, and early mortality from lymphoma further confounds the results in mice). In terms of concluding that the rodent studies are relevant to humans, however, the most interesting fact is that while there are species differences in the amount of BD at the target sites, both the rat and the mouse metabolized BD to the same reactive metabolites suspected of being the ultimate carcinogens.

5. Structure Activity

Although OSHA relied primarily on the animal bioassay data and human epidemiologic studies to reach its conclusions regarding the carcinogenicity of BD, in addition to this direct evidence, tests of structurally related chemicals support OSHA's conclusions.

Several metabolites or structurally related chemicals have been tested in whole animal bioassays. For example, the metabolite diepoxybutane (D,L and meso forms) produced skin tumors in mice when administered by application to the skin. The D,L racemate also produced local sarcomas in mice and rats by subcutaneous injection. L-1,2:3,4-Diepoxybutane was also carcinogenic in mice by intraperitoneal injection (Ex. 23–88). This information has led IARC to list diepoxybutane as a category 2B animal carcinogen (Ex. 23–89).

4-Vinylcyclohexene, the dimer of BD was tested in the NTP bioassay program by oral gavage. The studies in rats and in male mice were considered inadequate due to extensive and early mortality, but in female mice, vinylcyclohexene was associated with a markedly increased incidence of uncommon ovarian neoplasms (Ex. 23–90). Based primarily on this information IARC (Ex. 23–31) concluded that there is limited evidence for the carcinogenicity of 4-vinylcyclohexene to experimental animals.

Epoxybutane, which is structurally closely related to a suspected toxic metabolite of BD, epoxybutene, has also been tested for carcinogenicity in rodents by the NTP. This study found clear evidence of carcinogenicity in male F344 rats, with increased incidences of papillary adenomas of the nasal cavity, alveolar/bronchiolar carcinomas, and alveolar/bronchiolar adenomas or carcinomas (combined). Equivocal evidence of carcinogenic activity was found in female F344 rats. These animals developed papillary adenomas of the nasal cavity. In $B6C3F_1$ mice, there were nonneoplastic changes of the nasal cavity (Ex. 23–85).

In conclusion, the limited evidence that exists on the carcinogenic activity of suspected reactive metabolites and structurally related chemicals is completely consistent with the electrophilic theory of carcinogenesis as the mechanism of action for BD.

6. *Genotoxicity:* Short-term tests, such as assays for point mutations, chromosomal aberrations, DNA damage, and *in vitro* transformations are useful to screen for potential carcinogens, to reach a judgment on the carcinogenicity of a chemical, and to provide information on carcinogenic mechanisms (Ex. 23–70). The information presented below is concerned with the mutagenicity of BD, but it also includes a discussion of the mutagenicity of the reactive metabolites, 3,4-epoxybutene, and 1,2:3,4-diepoxybutane. The available evidence suggests that BD is mutagenic by virtue of its metabolism to mutagenic intermediates, adding further support to the conclusions drawn about BD's carcinogenic activity from the metabolism data and the information on structure activity relationships.

The system in which the greatest number of chemicals have been evaluated is the *Salmonella* microsome test where strains of genetically altered bacteria provide increased sensitivity to potential mutagens. Other microbal systems are also used to measure the capability of a chemical to interact with DNA to give rise to a mutagenic event.

BD at concentrations of 4–32 percent was mutagenic to *Salmonella typhimurium* TA1530 in the presence of a metabolic system (S9) from the livers of Arochlor- or phenobarbital-induced rats (Ex. 23–97). Although BD had previously been reported to be mutagenic to strain TA 1539 and TA 1535 in the absence of S9, this activity was subsequently attributed to cross-contamination by volatile mutagenic metabolites formed on plates containing S9 (Exs. 23–31, 23–99). This information indicates that BD is a base-pair promutagen in bacteria (Exs. 17–21, 23 71).

The mutagenic effects of BD have been examined in laboratory animals. No effects were observed in the bone marrow of rats exposed to BD gas at 100 ppm to 10,000 ppm for 6 hours/day for 2 days. In similarly exposed mice, however, there was a dose-dependent increase in bone marrow micronucleated cells and sister chromatid exchanges. Mice exposed to BD at 6.25 ppm to 625 ppm 6 hours/day for 10 days showed a significant increase in the frequencies of chromosomal aberrations and sister chromatid exchanges, a lengthening of the average generation time, and significant depression of the mitotic index in the bone marrow. In peripheral blood, there was a significant increase of micronucleated cell induction in polychromatic erythrocytes and in normochromatic erythrocytes (Ex. 23–71).

When male Wistar rats or $B6C3F_1$ mice inhaled radiolabeled BD, comparable amounts of ^{14}C radioactivity were found in the total liver DNA. The covalent binding of radioactivity to liver nucleoproteins of mice was about two times that in rats. The formation rate of reactive protein-binding metabolites was thus more important in the mouse, paralleling the higher metabolic rate in this species (Ex. 23–61).

The mutagenicity of BD has been attributed to two oxidative metabolites, epoxybutene and 1,2:3,4-diepoxybutane (Ex. 23–71). Epoxybutene, a monofunctional alkylating agent, is a direct mutagen in *S. typhimurium* strains TA1530, TA1535, and TA100 (Ex. 23–71). It is also a direct-acting mutagen in other bacteria (*Klebsiella pneumoniae* and *Escherichia coli*), and it induces sister chromatid exchanges and chromosomal aberrations in exposed mice (Ex. 17–21).

Diepoxybutane is a bifunctional alkylating agent, and as such it can form cross-links between two strands of DNA. It is mutagenic in bacteria (*K. pneumoniae* and *S. typhimurium*), fungi (yeast and *Neurospora crassa*), and the germ cells of *Drosophila melanogaster*. It also induces DNA damage in cultured hamster cells and in mice, is clastogenic in fungi and cultured rat cells, produces chromosome damage and breakage in *D. melanogaster* germ cells (Ex. 17–21). Diepoxybutane has induced sister chromatid exchanges in *in vivo* and *in vitro* assays involving Chinese hamster ovary cells, human lymphocytes and the bone marrow of exposed mice. Chromosomal damage, aberrations, or breakage has been seen from diepoxybutane exposure of human fibroblasts, lymphoblasts, and lymphocytes (Ex. 23–71). Therefore, the evidence indicates that the metabolites of BD are mutagens/clastogens in microbes and animals.

Citti *et al.* demonstrated the formation of an N–7 guanine adduct of epoxybutene after incubation with either deoxyguanosine or DNA (Ex. 23–63). The authors suggested that the formation of these adducts may account for the mutagenic effects of BD and its reactive metabolites (Ex. 17–21).

The findings that BD possesses mutagenic activity in the presence of microsomal enzymes, the fact that probable metabolites are direct-acting mutagens, and other evidence of genotoxicity of BD and its toxic metabolites are consistent with the electrophilic theory of carcinogenesis and support OSHA's conclusions that BD should be regarded as an occupational carcinogen.

E. Conclusions

OSHA's determination that BD is a potential occupational carcinogen was based primarily on the positive findings of chronic inhalation studies in rodents.

BD was carcinogenic to mice of both sexes, producing an unusual neoplasm of the heart. It also produced tumors in a dose-related manner at several other sites including lung, stomach, liver, mammary gland, and the lymphatic system. Rats exposed to BD by inhalation showed dose-related increases in the incidences of common and uncommon tumor types although the rats appeared to be less affected by BD exposure than the mice. The evidence in rodents is supported by epidemiologic findings from styrene-butadiene rubber workers and butadiene monomer production workers. These epidemiologic studies strongly suggest an association between lymphatic, and hematopoietic malignancy and exposure to BD. This evidence is further supported by findings of bone marrow toxicity in animals and the mutagenic activity of BD in bacteria in the presence of an exogenous metabolic system. Suspected metabolites of BD, epoxybutene and 1,2:3,4-diepoxybutane also have been shown to be genotoxic.

Exposure of rodents to BD resulted in ovarian atropy and uterine involution, testicular atropy and testicular tumors in mice and an increased incidence of tumors of the reproductive tract in rats suggesting that BD or some of its toxic metabolites may be capable of reaching the germ cells. The results of sperm head morphology and dominant lethality tests in mice are consistent with this conclusion that BD is a reproductive toxin in males and females. Life threatening or rare defects were observed in the fetal offspring of rats exposed to 8,000 ppm of BD during pregnancy and fetal growth retardation and increased incidences of morphologic variations occurred in a dose-related fashion in the offspring of mice exposed at 200–1,000 ppm. These studies are potentially indicative of developmental toxicity.

In summary, findings in humans and experimental animals exposed to BD are indicative of damage to the genetic material (DNA). Evidence from *in vivo* studies in animals or man shows that DNA damage may be manifested as increased incidences of cancer in the adult and mutation in offspring. Other adverse effects from BD exposure, such as acute sensory irritation, hematologic changes, and developmental toxicity are also suggested by the available evidence.

VI. Preliminary Quantitative Risk Assessment

A. Introduction

The United States Supreme Court, in the "benzene" decision, (*Industrial Union Department, AFL–CIO* v. *American Petroleum Institute*, 448 U.S. 607 (1980)) has ruled that the OSH Act requires that, prior to the issuance of a new standard, a determination must be made, based on substantial evidence in the record considered as a whole, that there is a significant risk of health impairment at existing permissible exposure limits and that issuance of a new standard will significantly reduce or eliminate that risk. The Court stated that "before he can promulgate any permanent health or safety standard, the Secretary is required to make a threshold finding that a place of employment is unsafe in the sense that significant risks are present and can be eliminated or lessened by a change in practices" (448 U.S. 642). The Court also stated "that the Act does limit the Secretary's power to require the elimination of significant risks" (448 U.S. 644).

The Court in the Cotton Dust case, (*American Textile Manufacturers Institute* v. *Donovan*, 452 U.S. 490 (1981)), rejected the use of cost-benefit analysis in setting OSHA standards, it reaffirmed its previous position in "benzene" that a risk assessment is not only appropriate, but also required to identify significant health risk to workers and to determine if a proposed standard will achieve a reduction in that risk. Although the Court did not require OSHA to perform a quantitative risk assessment in every case, the Court implied, and OSHA as a matter of policy agrees, that assessments should be put into quantitative terms to the extent possible.

The form a quantitative risk assessment takes depends upon the type of data available and the methodology available for analyzing the data. Data are available for quantifying three types of risk associated with occupational exposure to BD: carcinogenic risk, risk of reduced fertility (i.e. reproductive risk), and risk of developmental effects. For its preliminary assessment of the carcinogenic risk, OSHA has performed a low dose extrapolation using data from two animal inhalation bioassays. For its preliminary assessment of reproductive risk and risk of developmental effects, OSHA has used a safety factor approach with data from studies conducted on rats and mice.

B. Preliminary Assessment of Carcinogenic Risk

1. Choice of Data Base for Quantitative Risk Assessment

The first step in performing a quantitative assessment of carcinogenic risk is to choose a data set or sets which define the dose-response relationship. Two long-term BD inhalation bioassays have been completed: The NTP mouse bioassay (Ex. 23–1) and the HLE rat bioassay (Ex. 2–31). These studies are described in the discussion of carcinogenic health effects in this preamble. (NTP has very recently completed a second mouse bioassay, but complete data from this study are not yet available.) Despite the shortcomings of each of the bioassays, all five of the BD risk assessments submitted to OSHA used data from one or both of these animal studies to estimate the carcinogenic risk from exposure to BD.

The Office of Toxic Substances, U.S. Environmental Protection Agency (OTS) conducted an assessment of cancer risk to workers exposed to BD during BD monomer production and production of synthetic rubbers, plastics, and resins (Ex.17–5). For its risk assessment, OTS used only the mouse data. The reasons cited for this choice include: (1) the mouse is a more sensitive test species for BD than is the rat; (2) a quality control review had been done for the mouse bioassay at the time OTS wrote its risk assessment whereas none was available for the rat bioassay; (3) there was a greater amount of histopathological data available for the mouse than for the rat; and (4) the test article used by NTP had a much lower dimer concentration than the test article used by HLE.

The Carcinogenicity Assessment Group and the Reproductive Effects Assessment Group in the Office of Health and Environmental Assessment, U.S. Environmental Protection Agency (CAG) conducted an assessment of the mutagenicity and carcinogenicity of BD (Ex. 17–21). In order to quantify the risks associated with BD exposure, CAG used data from both the mouse and the rat bioassays. CAG believed, however, that the rat bioassay had deficiencies which limited its use as the primary data set for animal-to-man extrapolation and thus, used these data only for a sensitivity analysis. The deficiencies in the rat bioassay cited by CAG included the lack of individual rat pathology information available to CAG, the fact that the study had been neither peer-reviewed nor published at the time CAG did its risk assessment, the lack of an independent data quality evaluation for this study, and the uncertainty regarding the number of organ tissues actually examined by the study's pathologists. CAG acknowledged that the mouse study also had deficiencies which stemmed from less than strict adherence to Good Laboratory Practices, but it noted that NTP considered the mouse

bioassay to provide clear evidence of carcinogenicity, the highest classification in NTP's system of categorizing evidence of carcinogenicity. On this basis, CAG chose the mouse bioassay as its primary data source for quantifying risk.

Under contract to OSHA, ICF/Clement (ICF) prepared a document characterizing the risk associated with occupational exposure to BD (Ex. 23–19). Like OTS, ICF used only the mouse data for its quantitative risk assessment. The choice of this data set was based upon ICF's decision to use individual tumor data for some of its analyses; ICF felt that the NTP study provided more detailed and better documented information on the incidence of individual tumors than did the HLE study. In addition, ICF, like CAG, did not believe that the rat bioassay had been adequately validated and cited its uncertainty about the classification of the rat mammary tumors. ICF acknowledged the methodological problems of the NTP bioassay but felt that any bias these problems might introduce to the study's results would be a bias towards underestimation of the true risk associated with BD exposure.

A fourth risk assessment was performed by Environ Corporation for the Chemical Manufacturer's Association (CMA) (Ex. 28–14). Environ estimated risks using both the mouse and the rat data, but felt that estimates of risk based on the rat data would be less uncertain than estimates of risk based on the mouse data. Environ based this judgement on the methodological problems of the NTP mouse bioassay and its belief that the early mortality experienced by the mice and the stress possibly experienced by the mice would contribute to the uncertainty of the estimated risks. Furthermore, Environ believed that the maximum carcinogenic response was reached in the mice at 625 ppm as suggested by the fact that the low and high dose mouse groups had nearly identical numbers of tumor bearing animals. The only flaw in the rat study cited by Environ was that because BD absorption is saturated at 1000 ppm in the rat, Environ believed it was impossible to estimate with accuracy either the internal or effective dose at 8000 ppm in the rat.

The final risk assessment submitted for OSHA's consideration was performed by Dale Hattis and John Wasson at the Center for Technology, Policy, and Industrial Development at the Massachusetts Institute of Technology under a cooperative agreement with the National Institute for Occupational Safety and Health (NIOSH) (Ex. 29–3). It is a pharmacokinetic/mechanism-based analysis of the carcinogenic risk associated with BD and relies upon both the mouse and the rat data. The Agency is continuing to review this risk assessment, and therefore it is not included in the subsequent risk assessment discussion. The Agency intends to integrate public comments received during and after the hearings, and complete its analysis and conclusion prior to publication of the final standard.

OSHA believes that both the NTP mouse bioassay and the HLE rat bioassay demonstrate the carcinogenicity of BD and that both provide adequate data on which to base a quantitative risk assessment despite their problems. Both of these studies have qualities which make their data suitable for quantifying risk from occupational exposure: Exposure levels were documented; the routes of exposure were the same as is found in most occupational settings (i.e., inhalation); concurrent controls were used; animals were exposed to two different levels of the test substance; and statistically significant excesses of malignant neoplasms were observed in the exposed groups. Like CAG, however, the Agency has decided to base its "best" estimate of risk on the mouse data and to use the rat data to define a range of risks. This decision is based on a number of factors.

First of all, the decision to use the mouse data as the primary data set for quantifying risk is consistent with three of the four risk assessments reviewed by OSHA. Only Environ took a different position. OSHA, however, rejects Environ's argument that the maximum carcinogenic response was reached in the mice at 625 ppm. Environ's argument, based on the observation that all exposed mouse groups had nearly identical numbers of tumor bearing animals, ignores the dose-response relationship seen at almost every site where tumors among exposed mice were significantly elevated over controls.

Another factor which supports use of the mouse data as the primary data set for quantifying risk is that the NTP study has undergone two independent audits. The first audit, conducted by an NTP audit team, originally found discrepancies in the study data of sufficient magnitude to conclude that the data were not appropriate to support firm conclusions about the toxicological potential of BD (Ex. 17–23). Problems included the possible exposure of test animals to chemicals other than BD, the possible mix-up of animals among BD exposure groups, and the poor quality of animal husbandry practiced in the laboratory by the staff of Battelle Pacific Northwest. Battelle, however, was sufficiently able to resolve discrepancies in the data, (Ex. 17–24), for the NTP audit team to revise its conclusion and consider the bioassay data adequate to assess the carcinogenicity of BD (Ex. 22–3, Attachment 4).

The problems uncovered in this first study audit which would have the greatest impact upon OSHA's assessment of risk are the possible exposure of test animals to chemicals other than BD and the possible mix-up of animals among BD exposure groups. OSHA has evaluated the potential impact of these deviations from Good Laboratory Practices on any estimate of risk the Agency might derive from these data and has concluded that these deviations would not materially affect those estimates of risk. Even if these problems had not been resolved, OSHA believes their effect would be to cause the Agency to underestimate the carcinogenic risk from occupational exposure to BD. For example, if control animals were mixed up in the exposure groups, the effect would be dilution of the tumor incidence of the exposure group, consequently underestimating the risk, as was noted by ICF (Ex. 23–19). On the other hand, if animals from the exposure group were mixed up in the control group, the result would be an elevation of the tumor incidence in the control group. That would decrease the difference in tumor incidence between the exposure and control groups, again resulting in an underestimate of the risk associated with exposures to BD.

The second audit of the NTP bioassay was conducted by CMA (Ex. 17–25). The issues raised in that audit have been answered by NTP (Ex. 22–3) and by OSHA in its Advanced Notice of Proposed Rulemaking (51 FR 35003). While these issues are troublesome, OSHA does not believe they can explain the striking carcinogenic response observed in the mice. This position is supported by the preliminary results from the second NTP mouse bioassay which appear to replicate the results of the first bioassay (Ex. 23–101). OSHA would prefer to base its regulations on data from studies which adhere to Good Laboratory Practices, but OSHA does not believe that the deviations from the study protocol which occurred in the first NTP bioassay invalidate the conclusions of the study. Therefore, OSHA has chosen to rely upon the mouse data for its "best" estimate of risk.

In contrast to the mouse bioassay, criticisms of the rat bioassay put forth by OTS, CAG, and ICF have not been answered to OSHA's satisfaction. In addition, OSHA has several criticisms of its own. For example, OSHA is concerned about the possible lack of comparability among the male rat groups as discussed in the carcinogenic health effects section of this preamble. Another example is that although pathology reports are available for each individual rat used in the study, the site-specific incidence of tumors presented by HLE at the end of Volume I of its report cannot be reconciled with a count from the individual pathology reports. Different tumor counts from the individual pathology reports have produced different estimates of tumor incidences. Environ, for example, reported the incidence of uterine/cervical stromal sarcoma in the female rats as 1 for controls, 5 for the low dose group and 7 for the high dose group. Using the same pathology reports, however, ICF found the incidence of this tumor to be 1 for controls, 4 for the low dose group, and 5 for the high dose group.

As CAG noted, another issue of concern is that it is impossible to determine the exact number of animals examined at each site. For example, Table 31 in the Hazleton report gives 198 as the number of thyroid tissues examined histopathologically for the low dose female group. It is unclear, however, whether at least one slide from each animal in that group was examined at this site or whether two slides were examined for 99 animals in that group and one animal was never examined. This has important implications for quantitative risk assessment.

Another criticism is that although the HLE study has been published, it has not been subjected to a complete pathology peer review. Only the diagnosis concerning thyroid tumors was peer reviewed. The NTP study, on the other hand, has been subjected to such a review. As ICF discussed, it is possible that neoplasia in endocrine organs of the rats may have been over-diagnosed. HLE reported diagnoses in neither control nor high dose group animals of hyperplasia of thyroid follicular cells, adrenal medulla, adrenal cortex, pancreatic islets, and pituitary. Only two diagnoses of thyroid C-cell hyperplasia were reported. This is unusual, for hyperplasia in these organs is a common occurrence in aged rats. An additional issue is that the number of pathologists performing histopathological interpretation of tissues is unclear. Four pathologists are listed in the report, but the role of each pathologist has never been fully explained. Most carcinogenicity bioassays use only one pathologist to read all slides of a species to assure that there is consistency in the diagnosis of neoplastic and non-neoplastic lesions.

Finally, OSHA believes that the scope and the results of the HLE study audit are limited. Blocks and slides were checked for only ten animals (2%) from the study. In comparison, NTP conducted a 100% slide-block comparison for the high dose and control mice in its study. Furthermore, 74 of the individual animal pathology reports (12%) were not available to the study auditors thus making it difficult to verify that the study's final report was an accurate reflection of the raw data.

Despite these problems, OSHA believes that the HLE rat study demonstrates the carcinogenicity of BD and should not be ignored. These unresolved problems, however, mean that there will be greater uncertainty in risk estimates derived from the rat data than in risk estimates derived from the mouse data. Therefore, like CAG, OSHA will use the rat data to define a range of risks from occupational exposure to BD.

Choosing a data set for quantitative risk assessment entails deciding not only which species is most appropriate but also which sex of a species is most appropriate. OSHA believes that the female mouse and the female rat provide better data on which to base its estimates of risk. Traditionally, both sexes of a species are considered in order to obtain a range of risk estimates. In this case, however, it is not necessary to consider both sexes for this reason because OTS, CAG, ICF, and Environ provide OSHA with that range of risk estimates. Environ posed the question of whether or not it was appropriate to use absorption data from male test animals to estimate absorbed dose in female test animals. OSHA notes that neither CAG nor ICF thought this was inappropriate, and Environ thought is was inappropriate only for the mice and not for the rats.

OSHA believes that there are compelling reasons to choose the females of each species for its quantitative risk assessment. First of all, there is a clearer dose-response relationship among the female mice than among the male mice. This is true not only for total tumor incidence but also for almost every site-specific tumor incidence. OSHA is particularly interested in using the heart hemangiosarcoma incidence data as part of its quantitative risk assessment because heart hemangiosarcomas are so rare that there can be little doubt their occurrence is associated with anything but exposure to BD. OSHA believes that there may be less uncertainty in risks derived from these incidence data. The data on heart hemangiosarcoma incidence show a clearer dose-response relationship for female mice than for male mice, so OSHA will use the female mice for its quantitative risk assessment.

OSHA prefers the female rat to the male rat because, as discussed previously, there appears to have been some failure in the randomization process for male rats in the HLE study and the low dose rats appear to have been healthier than the control rats. When exposure groups are not comparable across all important factors, it is impossible to reach any sound conclusions about the carcinogenicity of a test substance. OSHA has greater confidence in risk estimates based on the female rat data and thus will use the female rat data to estimate risks.

2. Measure of Dose

Quantitative risk assessments based on animal data are performed under the assumption that animals and humans have equal risks from lifetime exposures to a chemical when exposure is measured in the same unit for both species. Opinions vary, however, on what is the correct measure of exposure. For site-of-contact tumors, a ppm-to-ppm conversion is a generally accepted measure of dose. For systemic tumors, commonly used dose conversions include mg/kg/day, mg/surface area/day, and mg/kg/lifetime. When pharmacokinetic or metabolic data are available, these data should be used to estimate internal dose. By using all available information, the uncertainty associated with estimating risks across species can be reduced.

BD absorption data is available for both $B6C3F_1$ mice and Sprague-Dawley rats. In 1985 NTP reported results from a BD absorption study using both these species (Ex. 23–7 and Ex. 23–8). Three groups of 30 male rats were exposed to concentrations of ^{14}C–BD at 70, 950 and 7100 ppm, and three groups of 30 male mice were exposed to concentrations of ^{14}C–BD at 7, 80 and 1040 ppm. All groups of animals were exposed for six hours except the high dose rat group and the middle dose mouse group which were exposed for only five and one-half hours.

The amount of BD absorbed by each group of rodents was measured as was the volume of air inhaled. These data, along with other data relevant to the calculation of experimental dose, are presented in Table 17.

TABLE 17.—DATA FROM THE NTP STUDY OF 1,3-BUTADIENE ABSORPTION IN SPRAGUE-DAWLEY RATS AND B6C3F[1] MICE.

	Exposure concentrations		Mean weight (kg)	Vol air inhaled (L)	BD inhaled (μg)	BD inhaled (μg/kg)	BD absorbed		Percent
	(ppm)	(μg/L)					μg	μg/kg	
Rats	70	125	.404	102.0	12,750.0	31,559.41	881.83	2,182.75	6.9
	950	1,700	.404	99.0	168,300.0	416,584.16	3,500.27	8,664.03	2.1
	7,100	12,800	.368	72.0	921,600.0	2,504,347.83	13,146.30	35,723.64	1.4
Mice	7	13	.0269	7.1	92.3	3,431.23	48.69	1,810.04	52.8
	80	145	.0266	12.9	1,870.5	70,319.55	173.12	6,508.27	9.3
	1,040	1,900	.0289	12.4	23,560.0	815,224.91	1,033.31	35,754.67	4.4

The NTP absorption study demonstrated that the rate of BD absorption in rodents is inversely related to exposure concentration. As exposure levels increase, the percent of dose absorbed decreases. It can be shown that the rate of change in BD absorption is very similar for the two rodent species, but the mouse absorbs about three and one-half times the amount a rat absorbs at the same nominal exposure level.

Using the absorption data, calculation of experimental dose is a two step process. First, it is necessary to estimate absorbed dose, and then it is necessary to adjust the absorbed dose to a continuous dose as required by most quantitative risk assessment computer programs. All of the risk assessments submitted to OSHA used the BD absorption data except the OTS risk assessment which assumed 100% absorption and used a ppm-to-ppm conversion.

The other three risk assessments, CAG, ICF and Environ, used the BD absorption data to calculate experimental dose by regressing some measure of absorbed BD on some measure of BD exposure. These risk assessments differed, however, in their choice of measure. For example, ICF measured absorbed dose as a percent of exposed dose whereas CAG measured absorbed dose in μg/kg. When both the dependent and independent variables are transformed using a log transformation, their relationship is remarkably linear regardless of choice of measure.

CAG and Environ used the same model to relate exposed dose to absorbed dose. This model, which we shall call the CAG model, is given by:

$$\text{Log (}\mu\text{g/kg BD absorbed)} = a + \beta \text{ Log (ppm BD exposed).}$$

This model was fit separately for the mice and the rats, and for both sets of data from the NTP absorption study, there was a good linear fit (for mice, $R^2 = .997$; for rats, $R^2 = .992$). The lines fit to these two sets of data had almost identical slopes (β), but their intercepts (a) were different.

ICF used a different linear model to relate exposed dose to absorbed dose. It chose the model:

$$\text{Log (ppm BD exposed)} = a + \beta \text{ Log (\% BD absorbed).}$$

Because ICF used only the mouse data for its quantitative risk assessment, this model was fit only to the mouse data. Like the CAG model, this model showed a strong linear relationship between the dependent and independent variables ($R^2 = .937$). Note, however, that ICF's choice of dependent and independent variables are quite different from those used by CAG. While CAG used a linear model to relate absorbed dose measured in μg/kg to exposed dose measured in ppm, ICF used its linear model to relate exposed dose measured in ppm to percent of dose absorbed. Like OTS, ICF measured effective dose in ppm, but unlike OTS, ICF adjusted for absorption. It should be added that ICF never really uses the model it proposes. After fitting the model to the data, it simply states that an absorption rate of 5% will be used for BD exposures of 625 and 1250 ppm because of the uncertainty of the estimate.

OSHA believes that given the information available on BD, estimates of experimental dose should account for differing absorption rates at different exposure levels and across different species. OSHA believes further that a mg/kg/day conversion is more appropriate than a ppm-to-ppm conversion because of the systemic nature of the tumors observed in both animal bioassays. As an alternative to either the CAG or ICF model, OSHA proposes that BD absorption be modeled by:

$$\text{Log (}\mu\text{g/kg BD absorbed)} = a + \beta \text{ Log (}\mu\text{g/kg BD inhaled).}$$

This model differs from the other models in its choice of independent variable. By measuring exposure as μg/kg BD inhaled, we use more of the information available to us, namely weight and inhalation volume, and thus can somewhat reduce the uncertainty associated with our estimate of experimental dose. The measure μg/kg BD inhaled is available from the NTP absorption study and can be easily estimated using the data available from the mouse and rat bioassays. Like the CAG and ICF models, this model shows a strong linear relationship between the dependent and independent variables for both sets of data (for mice, $R^2 = .980$; for rats, $R^2 = .988$).

Once absorbed dose has been estimated, converting it to a continuous dose is straightforward. For the CAG and OSHA models, the output is absorbed dose per day. Thus, dose needs to be adjusted only by a factor of 5/7 to account for the exposure schedule of five days per week. The experimental doses used by OTS and ICF must also be adjusted also by a factor of 5/7, but in addition, dose must be adjusted by a factor of 6/24 to account for the exposure schedule of 6 hours per day.

Because the NTP mouse bioassay was terminated early, OTS performed yet another adjustment on its estimate of experimental dose to account for this. The adjustment, given as $(L_e/L)^3$ where L_e is length of exposure and L is life expectancy, is justified on the grounds that if exposure had continued, the age-specific cancer rate would have continued to increase as a constant function of the background rate. CAG and ICF also used this adjustment to account for early termination of the study, but an adjustment of $(L/L_e)^3$ was applied to the risks and not to the dose.

OSHA does not believe that this adjustment for early mortality is necessary for estimating risks from the mouse data. The NTP bioassay was terminated early due to high mortality primarily from tumors. If the study had been terminated early for other reasons, then this adjustment would be appropriate, but OSHA does not believe that it is necessary to adjust for tumors which might have occurred had the mice not developed tumors and died.

Table 18 presents the different estimates of the absorbed and continuous doses used in the risk assessments submitted for consideration. Note that CAG and Environ used the same estimates of experimental dose.

TABLE 18.—EXPERIMENTAL DOSES FOR QUANTITATIVE RISK ASSESSMENT[a]

	Sex	OTS[b] (ppm)	ICF (ppm)	CAG (Environ) (mg/kg)	OSHA[c] (mg/kg)
Rats:					
1,000 ppm	M	N/A	N/A	10.5 (7.75)	8.06 (5.76)
1,000 ppm	F	N/A	N/A	10.5 (7.75)	8.96 (6.40)
Rats					
8,000 ppm	M	N/A	N/A	37.1[d] (26.5)	29.78 (21.27)
8,000 ppm	F	N/A	N/A	37.1[d] (26.5)	33.78 (24.13)
Mice:					
625 ppm	M	625 (21.43)	31.25 (5.6)	25.7 (18.4)	22.01 (15.72)
625 ppm	F	625 (22.52)	31.25 (5.6)	25.7 (18.4)	22.63 (16.16)
Mice					
1,250 ppm	M	1,250 (42.86)	62.50 (11.2)	38.9 (27.8)	31.40 (22.43)
1,250 ppm	F	1250 (45.04)	6.50 (11.2)	38.9 (27.8)	33.34 (23.81)

[a] Dose is daily internal dose. The numbers in parentheses are dose adjusted for continuous exposure.
[b] OTS adjusted experimental dose for early termination of the NTP study in addition to converting dose to continuous dose.
[c] Weights used are the mean weight for each sex and exposure group as measured at the mid-point of each bioassay.
[d] Environ reported an absorbed dose of 38.5 mg/kg for 6 hours exposure.

3. Measure of Carcinogenic Response

In most animal bioassays, exposure to chemical carcinogens is usually associated with elevated tumor incidence at one or two specific sites. BD is unusual in that it is associated with significantly elevated tumor incidence at multiple sites in both mice and rats. There is some debate as to whether tumors at multiple sites should be pooled to estimate overall carcinogenic response or whether only site-specific tumor incidence should be considered. In its Guidelines for Risk Assessment, EPA recommended that tumor sites or types should be pooled to obtain a total estimate of carcinogenic response. Others argue, however, that tumor sites should not be combined because of the differences in metabolic response among organs in the body.

In the past, OSHA has considered both pooled tumor incidence and site-specific tumor incidence as its measure of carcinogenic response. This is the first time, however, that OSHA has proposed regulating a substance associated with tumor induction at so many sites. OTS, CAG, ICF, and Environ all used pooled tumor incidence as their measure of overall carcinogenic response. For each of these risk assessments, incidence in each exposure group was measured as the number of animals bearing one or more tumors at any site where incidence for tumors at that site was significantly or nearly significantly elevated in one exposure group over incidence in controls divided by the number of animals at risk. In addition, OTS and ICF considered site-specific tumor incidence data to obtain a range of risk estimates. For example, OTS estimated risks using male mouse circulatory hemangiosarcoma incidence data, and ICF estimated risks using data on each tumor type with significantly elevated incidence in male or female mice. Environ considered only pooled tumors, but it considered different combinations of tumors to form the pool. For male mice, Environ considered pooled tumor incidence with and without lymphoma incidence because it considered these tumors to be of questionable relevance to human risk. For male rats, Environ considered pooled tumor incidence with and without Zymbal gland carcinoma incidence because although incidence of this tumor was not significantly elevated, it was nearly significantly elevated in the high dose female rat group. For the female rat, Environ considered pooled tumor incidence with and without mammary fibroadenoma incidence because these tumors are not malignant.

In addition to pooling tumors, all of the risk assessments combined benign and malignant tumors in the lung, liver, and ovary of the mouse and in the pancreas, testes, and thyroid of the rat. Only ICF did not combine papillomas of the forestomach with carcinomas at that site; the other risk assessments combined these tumors.

OSHA agrees that pooled tumor incidence is an appropriate measure of carcinogenic response and that benign and malignant tumors in the lung, forestomach, liver, and ovary of the mouse and in the pancreas, testes, and thyroid of the rat should be combined. Thus, as its measure of overall carcinogenic response in mice, OSHA will use the number of female mice presenting one or more of the following tumors: Alveolar/bronchiolar adenoma or carcinoma; heart hemangiosarcoma; hepatocellular adenoma or carcinoma; forestomach papilloma or carcinoma; mammary gland acinar cell carcinoma; and ovarian granulosa cell tumor. The site-specific incidence for these tumors are given in Table 1.

For its preliminary risk assessment, OSHA is excluding lymphoma incidence from its measure of overall carcinogenic response. It has been suggested that the extreme lymphoma response observed in the male mice was promoted by an endogenous murine leukemia virus found in the B6C3F$_1$ mouse but not known to be present in man. By excluding the lymphoma incidence from its preliminary risk assessment, OSHA is neither endorsing this argument nor implying that these tumors are irrelevant in assessing human risk. Indeed, lymphomas are the primary neoplasms observed with increased incidence in the available epidemiological studies.

Furthermore, the Chemical Industry Institute of Technology (CIIT) has reported a 14% incidence of lymphomas in a group of NIH-Swiss mice exposed to 1250 ppm BD for 52 weeks (Ex. 23–59). The NIH-Swiss mice are not known to carry the murine leukemia retrovirus found in the B6C3F$_1$ mice. Nonetheless, to avoid focusing debate on the role of the murine leukemia retrovirus in lymphoma induction in B6C3F$_1$ mice, OSHA has excluded these tumors from its analysis and seeks comment on the appropriateness of using lymphoma incidence in its measure of the overall carcinogenic response to BD exposure in B6C3F$_1$ mice.

As its measure of overall carcinogenic response in rats, OSHA will use the number of female rats presenting one or more of the following tumors: Thyroid follicular adenoma/carcinoma; Zymbal gland carcinoma; and mammary gland fibroadenoma. After reviewing the individual pathology reports for the rats, the Agency does not agree with Environ's finding of a statistically significant increase in the incidence of uterine/cervical stromal sarcoma. Environ found one stromal sarcoma in the control group, five in the low dose group, and seven in the high dose group whereas OSHA's count agrees with ICF's count of one stromal sarcoma in the control group, four in the low dose group, and five in the high dose group. The Agency believes that this difference in estimated incidence of uterine/cervical stromal sarcoma is due to a difference in interpretation of the individual animal pathology reports. Three rats were described as having stromal polyps. Environ must have included these polyps in their count of stromal sarcomas to have arrived at its incidence estimate. OSHA does not believe there is sufficent information in the individual animal pathology reports to make this determination, and thus did not include the polyps in its estimate of stromal sarcoma incidence.

The Agency agrees with CAG and Environ that Zymbal gland carcinoma incidence should be included in the measure of carcinogenic response in the rat. Although the increase in Zymbal gland carcinoma incidence is not quite statistically significant, these tumors are rare and should therefore be included.

In addition to these measures of overall carcinogenic response, OSHA will consider a second measure of response for each species. For the female mice, OSHA will use the site-specific incidence of heart hemangiosarcomas to estimate risks. The Agency is considering these tumors seperately because, as discussed above, they are so rare there can be little doubt that they are associated with anything but exposure to BD. As noted earlier, these tumors have been seen in only one of 2372 untreated male mice and only one of 2443 untreated female mice in two-year studies in the NTP Carcinogenesis Program (Ex. 23–1). For the female rats, OSHA will use pooled tumor incidence excluding mammary fibroadenomas to estimate risks. The Agency is considering this alternative measure of carcinogenic response for the female rats because it is interested in knowing how exclusion of these tumors will affect its estimate of risk.

Although all four risk assessments used the same measure of overall carcinogenic response, the actual numbers used in their low-dose extrapolations differ considerably. For example, OTS used "life-table" adjusted incidence rates instead of observed rates in its quantitative risk assessment. CAG and ICF used the number of necropsied mice surviving until the first lymphoma death at week 20 as their measure of animals at risk, whereas Environ used the total number of necropsied mice. The reader is referred to each of these risk assessments for the specific rates used.

For its low-dose extrapolation, OSHA will use the observed incidence as its measure of incidence. For its measure of animals at risk, OSHA will use the number of necropsied animals surviving to the week of the first death of an animal with any of the pooled tumors. The first female mouse that died and had at least one of the tumors OSHA is using for its pooled tumor analysis died at week 41 of the NTP study. This mouse presented a heart hemangiosarcoma, so the number of female mice at risk will be the same for the pooled tumor analysis and the heart hemangiosarcoma analysis. The first female rat which died and had at least one of the tumors OSHA is using for its pooled rat tumor analysis died at week 56 of the HLE study. This rat presented a mammary fibroadenoma, so for the pooled rat tumor analysis, the number at risk will be the number of rats surviving to week 56. For the analysis of the rat data excluding the mammary fibroadenomas, the number at risk will be the number of necropsied rats surviving to week 72. The actual numbers to be used for low-dose extrapolation are presented in Table 19.

TABLE 19.—INCIDENCE OF TUMORS IN FEMALE B6C3F$_1$, MICE AND CD RATS TO BE USED IN QUANTITATIVE RISK ASSESSMENT

	Controls	625 ppm	1,250 ppm
Female Mice:			
Pooled Tumors [a]	3/47 (6.4%)	23/38 (60.5%)	41/45 (91.1%)
Heart Hemangiosarcomas [b]	0/47 (0%)	11/38 (29.9%)	18/45 (40%)
	Controls	1,000 ppm	8,000 ppm
Female Rats:			
Pooled Tumors [c]	40/99 (40.4%)	77/97 (79.4%)	72/96 (75%)
Pooled Tumors excluding Mammary Fibroadenomas [d]	0/90 (0%)	4/85 (4.7%)	15/82 (18.3%)

[a] Numerator is number of mice with at least one of the tumors listed in Table 1 except lymphoma; denominator is number of mice surviving to week 41.
[b] Numerator is number of mice with heart hemangiosarcomas; denominator is number of animals surviving to week 41.
[c] Numerator is number of rats with at least one mammary fibroadenoma, thyroid follicular adenoma/carcinoma, or Zymbal gland carcinoma; denominator is number of animals surviving to week 56.
[d] Numerator is number of rats with thyroid follicular adenoma/carcinoma and/or Zymbal gland carcinoma; denominator is number of animals surviving to week 72.

4. Estimation of Occupational Dose

The purpose of low dose extrapolation is to estimate risk of death from cancer at a variety of proposed occupational doses. This requires that the occupational doses be converted into units comparable to those in which experimental dose is measured.

As discussed earlier, OSHA first converted experimental dose measured in ppm into inhaled dose measured in μg/kg. Then, using the BD absorption data, OSHA estimated absorbed dose for each inhaled dose. These two steps must again be followed to convert occupational dose measured in ppm into the appropriate units.

A dose of one ppm BD is converted into an equivalent dose measured in mg/m^3 using the equation:

$$1 \text{ ppm BD} = \frac{\text{Molecular Weight BD}}{24.45} = \frac{54.1}{24.45} \text{ mg/m}^3 \text{ BD}$$

Given a worker weighing 70 kg, breathing 9.6 m^3 of air per eight hour work day, and exposed to dose Y ppm BD, his inhaled dose of BD in mg/kg is given by:

$$\text{Y mg/kg BD inhaled} = Y \times \frac{54.1}{24.45} \text{ mg/m}^3 \times \frac{9.6 \text{ m}^3}{70 \text{ kg}}$$

Once inhaled dose is calculated and converted to μg/kg, absorbed dose is estimated by the model:

$$\text{Log } (\mu g/kg \text{ BD absorbed}) = a + \beta \text{ Log } (\mu g/kg \text{ BD inhaled})$$

proposed above. There are no data available on human absorption of BD. Thus, when risks for occupational doses are estimated from the mouse data, the estimates of a and β in the equation above are those derived from the NTP absorption study's mouse data, and when risks for occupational doses are estimated from the rat data, the estimates of a and β in the equation above are those derived from the NTP absorption study's rat data. In other words, when risks are derived from the mouse data, it is assumed that humans absorb BD at the same rate as do mice, and when risks are derived from the rat data, it is assumed that humans absorb BD at the same rate as do rats.

The model used by OSHA for estimating absorbed dose by inhaled dose is strictly an empirical model. The NTP inhalation study estimated absorbed dose at three inhaled dose levels, and the relationship between the log of absorbed dose and the log of inhaled dose is linear between the lowest and the highest dose used in the study. In the absence of other information, OSHA has extended the observed relationship between absorbed dose and inhaled dose to doses which are lower than those used by NTP in its inhalation study. This observed relationship between absorbed and inhaled dose is such that at some dose greater than zero, 100% absorption is achieved (i.e. the model predicts an absorbed dose equal to the inhaled dose). At doses lower than this, the model predicts absorbed doses greater than inhaled doses. This is because the model is not constrained by biological reality. If the model predicted an absorbed dose greater than the inhaled dose, OSHA assumed that absorption was 100% and that inhaled dose equaled absorbed dose. For the model derived from the NTP absorption study's mouse data, 100% absorption is reached at just over 2 ppm BD. For the model derived from the rat data, 100% absorption is reached at less than 1 ppm BD.

Once absorbed occupational dose has been estimated, it is necessary to convert the dose into a continuous dose as required by most quantitative risk assessment computer programs. For this final conversion, OSHA assumes that a person works 250 out of 365 days per year, and for 45 out of 74 years of life. The estimates of occupational dose derived by OSHA for use in its quantitative risk assessment are presented in Table 20.

TABLE 20.—ESTIMATES OF OCCUPATIONAL DOSE OF 1,3-BUTADIENE FOR USE IN QUANTITATIVE RISK ASSESSMENT [a]

Dose (ppm)	Inhaled dose [b] (mg/kg/8 hrs)	Rats	Mice
		Absorbed dose [c] (mg/kg/8 hrs)	Absorbed dose [d] (mg/kg/8 hrs)
1000	303.45	8.48 (3.53)	18.31 (7.63)
10	3.03	.46 (.19)	1.52 (.63)
5	1.52	.30 (.12)	1.04 (.43)
2	.61	.17 (.07)	*.61 (.25)
1	.30	.11 (.04)	*.30 (.13)

[a] Numbers in parentheses are the continuous doses. Continuous dose assumes exposure for 250/365 days and 45/74 years.

[b] Human inhaled dose assumes that a worker weighs 70 kg and inhales 9.6 m^3/8 hour work day.

[c] Absorbed dose is estimated from the model log (absorbed dose in μg/kg) = 1.07 + .63 log (inhaled doses in μg/kg).

[d] Absorbed dose is estimated from the model log (absorbed dose in μg/kg) = 2.99 + .54 log (inhaled doses in μg/kg).

* 100% absorption is achieved in the mouse at just over 2 ppm.

5. Selection of Model for Low Dose Extrapolation

Several approaches have been used to estimate cancer risk from exposure to toxic agents. A standard approach uses mathematical models to describe the relationship between dose (such as airborne concentration) and response (e.g. cancer). Generally, curves are fit to the data points observed at different exposure levels and these curves are used to predict the risk that would occur at exposure levels which were not observed. The shape of these curves is varied, ranging from linear extrapolations from the observed points through the origin (zero exposure and zero risk) to curves which may deviate far from linearity at the very highest of doses. The use of a particular model or curve can be justified in part by a statistical measure of "fit" to observed data points. That is, there are statistical tests which measure how closely a predicted dose-response curve fits the observed data.

The most commonly used model for low-dose extrapolation is the multistage model of carcinogenesis. This model, from a theory proposed by Armitage and Doll in 1961, is based on the biological assumption that cancer is induced by carcinogens through a series of stages. The multistage model is generally considered to be a conservative model because it is approximately linear at low-doses and because it assumes no threshold for carcinogenesis. "No threshold" means that any exposure to a carcinogen is associated with some amount of risk. "Approximately linear at low-doses" means that one unit of change in dose will result in one unit change in risk at low doses. This usually implies that the fitted curve approaches zero slowly.

The most common approach for using the multistage model is to assume that the dose-response curve is described by a polynomial of k–1 degrees, where k is the number of dose groups. The one-hit model is a special case of the multistage model where the value of k is fixed at k=1. This model is based on the assumption that there is only one stage in the carcinogenic process. In general, the one-hit model will produce estimates of risk which are larger than those produced by a multistage model of two or more degrees.

All of the risk assessments submitted to OSHA used the multistage model to estimate risks at low doses. Most of the analyses used the traditional k–1 stage model with the exception of OTS which used the one-hit model for all its analyses. CAG and ICF used the one-hit model in some of their analyses. CAG used this model for the pooled female rat tumor data, and ICF used this model for the pooled male mouse tumor data and for some of its site-specific analyses. In both the CAG and ICF risk assessments, the one-hit model was used only after the k–1 stage model was fit to the data and found to provide an inadequate fit. In each case, the high dose group was dropped from the analysis leaving only one exposure group and the control group. Thus, the one-hit model was the only appropriate model to use.

The risk assessment by Environ was the only risk assessment which considered other models in addition to the multistage model. For its analyses of the mouse data, Environ did not use the multistage model at all. Instead, it used the Hartley-Sielken time-to-tumor model to account for the less than lifetime exposure experienced by the mice in the NTP study. For its analysis of the rat data, Environ used the Mantel-Bryan and Weibull models in addition to the multistage model.

OSHA has consistently evaluated several models when performing quantitative risk assessments based on rodent bioassay results, but the Agency has shown a preference for the multistage model. OSHA has justified this preference on the grounds that the multistage model has the best empirical and theoretical justification for use in making "best estimates" of likely risk at specific doses. The multistage model is a mechanistic model of the form

$$P(\text{Cancer}) = 1 - \exp(-f(\text{dose})),$$

with f(dose) given by:

$$f(\text{dose}) = a + b_1(\text{dose}) + b_2(\text{dose})^2 + \ldots + b_k(\text{dose})^k.$$

The number of stages is specified by k, and the parameters a and b_i are estimated from the observed data. This model approximates the multistage process by the multiplicative linear function f(dose).

The multistage model is preferred not only because it incorporates the multistage theory of Armitage and Doll but also because it may be linear at low doses and assumes no threshold for carcinogenesis (i.e. any exposure is associated with some excess risk). Thus, it is a conservative model and its use is consistent with the position taken by the Office of Science and Technology Policy (OSTP) in its publication *Chemical Carcinogens; A Review of the Science and its Associated Principles* (50 FR 10371; March 14, 1985) that "when data and information are limited, and when much uncertainty exists regarding the mechanisms of carcinogenic action, models or procedures which incorporate low-dose linearity are preferred when compatible with the limited information."

Alternatives to the multistage model are the tolerance distribution models such as the probit model, the logit model, and the Weibull model. The Mantel-Bryan model used by Environ is a modified version of the probit model. These models attempt to describe the distribution of thresholds to carcinogens among individual members of a population. Although these models have been found to adequately model many types of biological dose-response data, as stated by Park and Snee, "it is an overly simplistic expectation to represent the entire carcinogenic process by one tolerance distribution" (Ex. 23–102).

The tolerance distribution models generally predict dose-response relationships which are sigmoid in shape (i.e. S-shaped). Thus, these models will approach zero more rapidly than a linear multistage model. This means that at low doses, these models will predict lower risks than will a linear multistage model. This is why the multistage model is described as more conservative than the tolerance distribution models.

Because the tolerance distribution models are sigmoid in shape, these models fit data well only when the data is also sigmoid in shape. The multistage model, on the other hand, may be linear at low doses, but can accommodate data which are linear or concave up at moderate doses. (A "concave up" dose-response line is shaped like a hockey stick. The line rises slowly at first but becomes quite steep after the point of inflection.) If the data are concave down, the one-hit model, a special case of the multistage model where the number of stages is one, can accommodate these data. (A "concave down" dose-response line is the mirror image of a "concave up" dose-response line. The line rises rapidly at first but flattens after the point of inflection.) The flexibility of the multistage model means that the model can provide a good fit to many empirical data sets. This flexibility is an additional reason for the Agency to prefer the multistage model for its quantitative risk assessment.

6. OSHA's Estimates of Risk

As described in the previous section, OSHA used the multistage model to estimate the risk of death from cancer due to occupational exposure to BD. Estimates were produced using a version of R.B. Howe and K.S. Crump's Computer Program Global 83 adapted for the microcomputer by M.S. Cohn of the U.S. Consumer Product Safety Commission.

OSHA used the four data sets presented in table 19 for its analyses. A one-hit model and a k–1 stage model were fit to each data set (for all four data sets, the model is a k–1=2 stage model). The results from OSHA's preliminary quantitative risk assessment are shown in table 21. Both the maximum likelihood estimate (MLE) of risk and the 95% upper confidence limit (UCL) on the MLE are presented. The MLE is a point estimate and represents that value which maximizes the likelihood of the risk. The 95% UCL represents a plausible upper bound below which the true risk is likely to be. Calculations of estimated deaths per 10,000 workers are based on extra risk.

TABLE 21.—ESTIMATES OF CANCER DEATHS PER 10,000 WORKERS EXPOSED TO 1,3-BUTADIENE [a]

Data	Stages	1 ppm	2 ppm	5 ppm	10 ppm	1000 ppm	X^{2} [b]
Pooled female mouse tumors	k=1	95	183	312	454	4301	4.02
		(120)	(230)	(393)	(570)	(5089)	(1)
	* k=2	0.6	2	7	15	1963	.54
		(80)	(153)	(263)	(383)	(4041)	(1)

TABLE 21.—ESTIMATES OF CANCER DEATHS PER 10,000 WORKERS EXPOSED TO 1,3-BUTADIENE [a]—Continued

Data	Stages	1 ppm	2 ppm	5 ppm	10 ppm	1000 ppm	X²[b]
Female mouse heart tumors	k=1	28	53	91	134	1502	1.4E-3
		(37)	(71)	(122)	(179)	(1961)	(2)
	[d] k=2	27	51	88	128	1468	4.3E-28
		(37)	(71)	(122)	(179)	(1961)	(1)
Pooled female rat tumors	k=1	66	115	197	310	4431	1.5E-26
		(90)	(156)	(266)	(418)	(5480)	(–)
	[e] k=2	16	29	48	75	1312	19.29
		(23)	(40)	(69)	(109)	(1836)	(1)
Pooled female rat tumors	k=1	3	6	10	16	285	.04
		(5)	(8)	(14)	(22)	(404)	(2)
	[f] k=2	3	5	9	14	258	7.9E-30
		(5)	(8)	(14)	(22)	(403)	(1)

[a] Estimates are derived from the multistage model. Numbers in parentheses are the 95% UCL estimates.
[b] Numbers in parentheses are degrees of freedom.
[c] For the one-hit model, q(0)=.063, q(1)=.074. For the two-stage model, q(0)=.064, q(1)=0, q(2)=.0038.
[d] For the one-hit model, q(0)=0, q(1)=.021. For the two-stage model, q(0)=0, q(1)=.021, q(2)=.0004.
[e] For the one-hit model, the high dose group was dropped and q(0)=.518, q(1)=.166. For the two-stage model, q(0)=.709, q(1)=.04, q(2)=0.
[f] Mammary fibroadenoma incidence excluded from this analysis. For the one-hit model, q(0)=0, q(1)=.008. For the two-stage model, q(0)=0, q(1)=.007, q(2)=.00005.

The first set of data to be analyzed was the pooled female mouse tumor data set. Both a one-hit and a two-stage model were fit to the data. The two-stage model gave a better fit, but the p-value associated with the goodness-of-fit chi-square from each model was greater than .01, so either model could be said to provide an adequate fit.

The one-hit model is often criticized for being too conservative, and as can be seen in Table 21, the estimates of risk derived from this model for these data are as much as 160 times greater than the estimates of risk derived from the two-stage model. In this case, however, the two-stage model may be criticized for not being sufficiently conservative. When fit to these data, the two-stage model had no linear term, (i.e. q(1)=0), with the result that the model is not linear at low doses. As can be seen, if we let .06 equal one unit of dose and we let .7 equal one unit of risk, then a change in two units of dose between .13 mg/kg BD (1ppm) and .25 mg/kg BD (2 ppm) results in a change in 2 units of risk. Between .25 mg/kg BD (2 ppm) and .43 mg/kg BD (5 ppm), however, a change in 3 units of dose results in a change of 7 units of risk. If the model were linear at these low doses, a change in 3 units of dose should result in a change of 3 units of risk.

The second set of data to be analyzed was the female mouse heart hemangiosarcoma data. The one-hit model provided an excellent fit to these data. The two-stage model also provided an excellent fit, and the addition of the q(2) term in the model had only a small effect on the MLEs and no effect on the UCLs.

For the pooled female rat tumor data, the two-stage model became a one-hit model (i.e. q(2)=0), and the fit was very poor. This was due to the fact that for this data set, incidence in the low dose group was higher than incidence in the high dose group. OSHA dropped the high dose group and fit a one-hit model to the remaining data.

The final data set to be analyzed was the pooled female rat tumor data excluding the mammary fibroadenomas. Here again, both a one-hit and a two-stage model were fit to the data, and both models provided an excellent fit. As with the female mouse heart hemangiosarcoma data, there was little difference between the MLEs and no difference between the UCLs derived from each model.

At the current OSHA PEL of 1000 ppm, the highest estimate of risk is given by the one-hit model fit to the pooled female rat tumor data including the mammary fibroadenomas as a measure of response and excluding the high dose group to achieve a better model fit. This estimate of 4,431 cancer deaths per 10,000 occupationally exposed workers is very close to the estimate of 4,301 cancer deaths per 10,000 workers given by the one-hit model fit to the pooled female mouse tumor data. The estimates of risk at 1000 ppm derived from the two-stage model applied to the pooled mouse tumor data, the one-hit model and the two-stage model applied to the female mouse heart hemangiosarcoma data, and the two-stage model applied to the pooled female rat tumor data including mammary fibroadenomas are remarkably consistent. These estimates range from 1300 to 1900 cancer deaths per 10,000 exposed workers. The lowest estimate of risk at the current PEL were given by the models applied to the pooled female rat tumor data excluding the mammary fibroadenomas, 258 to 285 cancer deaths per 10,000 exposed workers.

7. Other Estimates of Risk

In order to judge the reasonableness of OSHA's estimates of risk as compared to those derived in other risk assessments, estimates of cancer deaths per 10,000 workers due to occupational exposure to BD from those risk assessments are presented in Table 22. These numbers were either calculated in the risk assessments or derived from the risk assessments. Risks for exposures of 1, 5, and 10 ppm BD are presented. In reviewing this table, the reader should bear in mind that all of these estimates are based upon different assumptions. These different assumptions are discussed briefly below, but the reader is referred to the individual risk assessments for specific details.

TABLE 22.—ESTIMATES OF CANCER DEATHS PER 10,000 WORKERS EXPOSED TO 1,3-BUTADIENE FROM FOUR DIFFERENT RISK ASSESSMENTS [a]

Source	Data	Model	1 ppm	5 ppm	10 ppm
OTS[b]	Pooled male mouse tumors	One-hit	213	1022	1940
			(344)	(1585)	(2919)

TABLE 22.—ESTIMATES OF CANCER DEATHS PER 10,000 WORKERS EXPOSED TO 1,3-BUTADIENE FROM FOUR DIFFERENT RISK ASSESSMENTS [a]—Continued

Source	Data	Model	1 ppm	5 ppm	10 ppm
OTS[§]	Pooled female mouse tumors	One-hit	85	419	821
			(111)	(545)	(1060)
OTS[§]	Male mouse hemangiosarcomas	One-hit	40	198	392
			(57)	(281)	(554)
CAG[§]	Pooled male and female mouse tumors [b]	Multistage	16	175	482
			(175)	(844)	(1619)
CAG[§]	Pooled male rat tumors	Multistage	0	1	2
			(6)	(30)	(61)
CAG[§]	Pooled female rat tumors	One-hit	64	301	599
			(84)	(395)	(784)
ICF[§]	Pooled Male mouse tumors [c]	One-hit	2613	7839	*
			(3500)	(*)	(*)
ICF[§]	Pooled female mouse tumors	Multistage	859	2576	3435
			(1591)	(4773)	(6344)
Environ	Pooled Male mouse tumors [d]	Hartley-Sielken[e]	47	N/A	456
			(55)		(534)
Environ	Pooled male rat tumors [f]	Multistage	1	N/A	11
			(7)		(68)
Environ	Pooled male rat tumors [f]	Weibull	0	N/A	2
			(6)		(59)
Environ	Pooled male rat tumors [f]	Mantel-Bryan	2	N/A	48
			(4)		(88)
Environ	Pooled female rat tumors [g]	Multistage	6	N/A	58
			(8)		(79)
Environ	Pooled female rat tumors [g]	Weibull	6	N/A	57
			(8)		(79)
Environ	Pooled female rat tumors[g]	Mantel-Bryan	3	N/A	71
			(6)		(120)

§ = Only UCLs used in quantitative risk assessment. OSHA calculated corresponding MLEs. See text for details.
* = Estimate of number of deaths per 10,000 exceeds 10,000
N/A = Estimates of risk at 5 ppm not provided
[a] Numbers in parentheses are 95% UCL estimates.
[b] These numbers have not been adjusted for early termination of the study although CAG did so in its risk assessment.
[c] High dose group dropped from the analysis.
[d] Incidence of lymphoma excluded from pooled tumor incidence.
[e] Model is the Hartley-Sielken time-to-tumor model.
[f] Incidence of Zymbal gland carcinoma excluded from pooled tumor incidence.
[g] Incidence of mammary fibrcadenoma excluded from pooled tumor incidence.

The risk assessment by OTS presented only the 95% UCLs on risk for a variety of doses and occupational scenarios. Estimates were based on the pooled male mouse tumor data, the pooled female mouse tumor data, and the male mouse circulatory hemangiosarcoma data. Risks were derived from "life-table" adjusted incidence rates used with the one-hit model. Doses were based on a ppm-to-ppm conversion, 100% abosorption was assumed, and adjustment was to made to the experimental doses to account for early termination of the NTP bioassay.

OSHA calculated the MLEs associated with the 95% UCLs estimated by OTS for exposure of 8 hours per day, 240 days per year, for 40 out of 70 years. This exposure scenario was chosen because it is most like the one used by OSHA, thus facilitating comparison of estimated risks. OTS chose the one hit model because it was interested only in estimating the 95% UCLs, and the two-stage model gave negligible estimates of $q(2)$ and $q^*(2)$ when fit to the "life-table" adjusted incidence rates.

CAG was interested in estimating the unit risk associated with BD exposure. Estimates of $q^*(1)$ were derived from the pooled male mouse tumor data, the pooled female mouse tumor data, the pooled male rat tumor data, and the pooled female rat tumor data. Observed tumor incidence rates were used with the multistage model. For the pooled female rat tumor data, the high dose group was dropped, and a one-hit model was fit. Doses were based on a ppm-to-mg/kg/day conversion and varying absorption rates were assumed.

OSHA derived estimates of risk from the CAG risk assessment for different occupational doses using the equality 1 ppm BD = 2.25 mg/m^3 and CAG's assumptions that exposure occurs 8 hours per day, 240 days per year, for 45 out of 70 years; that a 35 g mouse breathes .043 m^3 of air per day; that a .70 kg rat breathes .354 m^3 of air per day; and that absorption at low doses is 54%. Risks were estimated using the computer program GLOBAL 82 by R.B. Howe and K.S. Crump. Following CAG, OSHA calculated the geometric mean of the MLEs derived individually from the male mouse data and the female mouse data. The same was also done for the UCLs. CAG reasoned that because the response was so similar between male and female mice, the geometric mean of the risks was an appropriate estimate. Although CAG adjusted its estimate of unit risk for early termination of the NTP study in its risk assessment, the numbers presented in Table 22 have not been adjusted.

ICF, like OTS, presented 95% UCLs for a variety of occupational exposure scenarios in its risk assessment. Estimates were based on the pooled male mouse tumor data, pooled female mouse tumor data, male mouse lymphoma data, and female liver tumor data. Only the results of the pooled tumor data are presented here. Estimates are based on observed incidences and are derived from the multistage model for the pooled female mouse tumor data and the one-hit model for pooled male mouse tumor data without the high dose group. Absorption is assumed to vary with dose, doses are based on a ppm-to-ppm conversion, and risks were adjusted for early termination of the NTP study.

OSHA calculated the MLEs associated with the 95% UCLs calculated by ICF for exposure of 8 hours per day, 240 days per year, for 45 out of 70 years estimated by ICF. The risk for exposure at 1 ppm for 45 years

was calculated and adjusted for early termination of the NTP study. That risk was multiplied by 5 and .6 to arrive at an estimate for exposure at 5 ppm where 60% absorption was assumed. The risk at 10 ppm, where 40% absorption was assumed, was calculated by multiplying the risk at 1 ppm by 10 and 4.

Environ presented both MLEs and UCLs in its risk assessment. Risks based on the pooled male mouse tumor data were derived from the Hartley-Sielken time-to-tumor model, and risks based on the pooled male and female rat tumor data were derived from the multistage, Weibull and Mantel-Bryan models. Environ's exposure scenario assumed exposure for 50 weeks per year, for 40 out of 70 years. Experimental dose was based on differing absorption rates for different doses, but a constant 50% absorption was assumed for occupational dose regardless of the nominal occupational dose. Doses were based on a ppm-to-mg/kg/day conversion.

The highest estimates of risk were given by ICF. These estimates are so high because the adjustment used by ICF to account for early termination of the NTP study increases risk estimates by approximately five times. In contrast, the adjustment used by OTS to account for early termination of the NTP study had a much less extreme effect on the estimates of risk. As noted earlier, OSHA does not believe that this adjustment is necessary in this case because the NTP mouse study was terminated early due to the large number of deaths from tumors. The lowest estimates of risk are given by CAG's application of the multistage model to the pooled male rat tumor data and by Environ's application of the Weibull model to the pooled male rat tumor data. These estimates are identical. With the exception of these two lowest estimates, all of the models, including those used by OSHA, predict risks in excess of 1 per 1000 at an occupational exposure of 10 ppm BD. Even at an occupational exposure of 1 ppm, most of the models predict risks greater than 1 per 1000. Models based on the rat data predict lower risks, but these are based either on the male rat data or on the female rat data excluding the mammary fibroadenomas.

8. Discussion

OSHA has chosen to rely upon the NTP mouse data for its "best" estimate of risk because the study has been subjected to two in-depth audits, and preliminary results from a second NTP inhalation bioassay indicate that the original study results can be replicated (Exs. 23–59 and 23–101). The Agency is reluctant, however, to base its "best" estimate of risk on the pooled tumor incidence among female mice. While the Agency acknowledges that the estimates of risk derived from the one-hit model fit to these data may be conservative, the Agency believes quite strongly that the estimates of risk derived from the two-stage model fit to these data are not sufficiently conservative to protect worker health. The two-stage model fit to the pooled female mouse tumor data is not linear at the doses of interest to the Agency. Rather, the model predicts a dose-response relationship which is concave up.

Low-dose extrapolation models describe dose-response relationships which may take one of three shapes: Concave up, linear, or concave down. A model which is concave up will predict risks at low doses which are smaller than those predicted by a linear model, while a model which is concave down will predict risks at low doses which are larger than those predicted by a linear model. Thus it follows that if a model which is concave up is selected to predict estimates of risk but the true dose-response relationship is linear or concave down, then the risks at low doses will be underestimated. On the other hand, if a model which is concave down is selected to predict estimates of risk but the true dose-response relationship is linear or concave up, then the risks at low doses will be overestimated. If a linear model is selected to predict estimates of risk, however, risks will be underestimated *only* if the true dose-response relationship is concave down. By choosing a linear model, OSHA selects a model between the two extremes. The Agency believes this preference is prudent public health practice.

At present, OSHA's "best" estimates of risk are those derived from the two-stage model fit to the female mouse heart hemangiosarcoma data. Because of the rarity of these tumors, the Agency is confident that the observed response is a measure of the carcinogenic potency of BD and that the risks derived from the two-stage model are valid estimates of the carcinogenic risk associated with occupational exposure to BD. OSHA prefers the two-stage model to the one-hit model because although the estimates of risk are almost identical, OSHA believes there is greater biological justification for the two-stage model.

The Agency is aware, however, that it may be underestimating the cancer risk from exposure to BD by basing its "best" estimate of risk on the female mouse heart hemangiosarcoma data. At 10 ppm BD, these data give an estimate of cancer death of 128 per 10,000 exposed. This is lower than almost every estimate of risk at 10 ppm in the risk assessments reviewed by OSHA. Only the estimate derived by CAG from the male rat data and the estimates derived by Environ from the pooled male rat tumor data and the pooled female rat tumor data excluding mammary fibroadenomas are lower at this exposure level. The same is true down to 5 ppm, but below this, CAG's estimate from the pooled male and female mouse tumor data is lower than OSHA's "best" estimate of risk. By relying upon the female mouse heart hemangiosarcoma data for its "best" estimate of risk, OSHA may be underestimating BD's carcinogenic potential.

C. Preliminary Assessment of the Risk of Reproductive Effects and Developmental Effects

Risk assessments employing safety factors have been used for assessing reproductive hazards for regulatory purposes (Exs. 23–72, 23–73); it is a conservative approach that takes into account the inherent limitations of animal studies in their ability to demonstrate adverse effects. Safety factors have the advantage that in the absence of a mechanism-based methodology, they provide a practical means for establishing tolerable exposure levels which are unlikely to be associated with adverse health effects in the human population. Moreover, the use of safety factors is justified because a finding of only resorptions or developmental delays in standard rodent assays does not necessarily ensure that a toxic substance will not cause more severe malformations in animals under other test conditions or in humans exposed in the workplace.

It is necessary to recognize the limitations of this approach. Safety factors rely on only one point of the dose-response curve, the no-observed-effect-level (NOEL). This is, perhaps, the weakest point in the curve, for although no effect is observed, it may be due to study design (e.g. exposure group size) and not the level of exposure. Furthermore, safety factors imply a population threshold which may or may not be plausible. That is, they imply that a level exists below which there is no risk of adverse health outcomes.

For certain outcomes, such as cancer, non-threshold models are usually assumed to apply. As discussed by the Office of Science and Technology Policy (OSTP) in its publication "Chemical Carcinogens; A Review of the Science and its Associated Principles," the

implicit assumption of thresholds in the use of a safety factor approach argues against this approach for cancer risk assessment (Ex. 23–70). OSTP noted that "even if the concept of individual thresholds could be supported, the well recognized genetic variability in the human population would effectively prevent the estimation of a general population threshold value. Moreover, given the high level of background cancer present in the human environment, it seems unlikely that one could rule out the possibility that a new chemical exposure, however limited, might augment an already mechanistic process and thereby produce a collective or additive exposure that exceeds the unknown threshold level" (Ex. 23–70).

This preliminary assessment estimates the human risks of developmental effects and reduced fertility resulting from exposure to BD. The analysis uses a safety factor approach based on rodent studies.

The selection of appropriate safety factors is based on the different doses needed to produce adverse effects in humans and animals. Examination of 7 chemicals causing developmental effects in humans indicated that, when the lowest-observed-effect level (LOEL) is expressed on a weight per unit weight per day basis, the minimally effective doses in humans versus test animals vary by ratios of 1 to 40 (Ex. 23–74). Humans, however, rarely have precisely the same array of developmental defects as animals exposed to the same agent. Thus, even though "equivalent response" is a measurable quantity, projections of human risk from animal data are tempered by the fact that the actual effects in humans may be either more or less severe than those in the animal model.

There are theoretical, as well as empirical, approaches that attempt to explain species differences by examining differences in metabolic and excretion rates. The rate of metabolism of foreign compounds in the body appears to depend on an animal's size. Smaller animals tend to metabolize and excrete toxins more rapidly than larger animals resulting in exposure of the critical organ to a smaller dose of the toxicant. Although there are numerous exceptions, the sensitivity of animals to toxicants varies generally with the 2/3 power of their weight. On this basis, humans would be about ten times more sensitive than most laboratory animals (Ex. 23–75).

Human populations are more variable than inbred laboratory animals. In order to protect the more sensitive individuals, an additional margin of safety of ten is often employed (Exs. 23–72, 23–75). This factor is arbitrary—it is not presently known how human sensitivity to BD or other developmental toxins varies.

In the absence of definitive data, risk assessments have applied theoretical considerations regarding species-to-species corrections and human variability to use a margin of safety of 100 (Exs. 23–72, 23–75). As a consequence, humans would be expected to be less frequently affected than experimental animals when their exposures are more than 100 times lower than the experimental exposures. Between one-tenth and one-hundredth the experimental exposures, there is a possibility that human risk could be as high as that of the animals tested, and at exposures greater than one-tenth those of the NOEL for animals, humans could even be at greater risk of adverse effects than the experimental animals.

For BD, assessments of the risks of developmental and reproductive toxicity must be based on information from studies conducted using rats and mice. Teratogenic effects were found in rats exposed at 8,000 ppm; the NOEL for rats in two separate experiments was 1,000 ppm. At this level, mice did not demonstrate fetal malformations, but there were skeletal defects and reduced ossification at 1,000 ppm, suggesting that this level for mice is, at best, a no-observed-adverse effect level (NOAEL) for teratogenic effects. Application of a safety factor of 100 to the 1,000 ppm NOAEL indicates that BD exposures below 10 ppm should present little, if any risk of teratogenic effects to the offspring of workers exposed to BD under conditions that would be permitted by the proposed standard.

For BD, the frequency of developmental effects increased with dose. The nature and severity of the effects also changed with dose. In mice, body weight gain of male fetuses was affected at 40 ppm, the lowest dose tested. The body weights of female mice were significantly reduced only when concentrations reached or exceeded 200 ppm; the NOEL was 40 ppm. Since body weight reductions in the male mice were not severe or life-threatening, OSHA accepted 40 ppm as the NOAEL. Use of a safety factor of 100 suggests that there may be some residual risks of developmental toxicity in the offspring of humans exposed to BD at 2 ppm. These effects should be mild and reversible, however, if the results in mice are directly extrapolatable to humans.

There is substantial evidence in mice to suggest that BD poses a hazard to the adult from reduced fertility (See Health Effects section), and consequently, probably also causes changes in secondary sex characteristics of offspring. These changes in offspring would be predicted from evidence of testicular toxicity. The NOEL for morphologically abnormal sperm heads was 200 ppm; for dominant lethality, the LOEL was 200 ppm (no NOEL found); and for testicular atrophy, the NOEL was 200 ppm 65 weeks into a 2 year study. In female mice, the NOEL for ovarian atrophy was 6.25 ppm with a LOEL of 20 ppm. Ovarian atrophy, if sufficiently extensive, would cause a failure of implantation or early death of the fetus. This effect appears, however, to be a more sensitive indicator of adverse effects than some of the tests of males, such as dominant lethality, with a LOEL of 200 ppm. Use of a safety factor of 100 to project human risk from the animal data suggests that humans may remain at increased risk of reduced fertility from BD exposures that would be permitted by the proposed revision of the PELs.

In summary, OSHA's assessment of the reproductive and developmental risks associated with BD exposure indicates that a TWA concentration limit of 2 ppm will not completely protect against these hazards. It is known from tests conducted on certain other reproductive toxins that short-term high dose exposures may pose special dangers not otherwise indicated. However, there is no information on BD regarding dose-rate and reproductive or developmental toxicity and this possibility was not considered in proposing a STEL for BD.

For BD's reproductive and developmental effects, the mouse appears to be more sensitive than the rat to concentrations of BD in the air. If humans are more like the rat than the mouse, perhaps a lower margin of safety could be applied to predict human risk. In contrast, however, evidence of developmental effects and reduced fertility are present at the lowest dose studied in some BD experiments, so that a LOEL, and not a NOEL, must be employed in parts of the analysis of risk. In such circumstances, there would always be concern that the use of safety factors could underpredict the risk to humans.

Other uncertainties are imposed because of limitations inherent in the BD test data. Some studies showing effects that would influence fertility were designed for other purposes (e.g. carcinogenicity); others were limited in their ability to detect adverse changes because of limitations of protocol. In some cases, a NOEL was not found, and OSHA had to rely on information from

the lowest dose tested. Presently, evidence of reproductive and developmental toxicity is limited to tests conducted on mice and rats; no other mammalian species has been tested, and there is no evidence in humans. In addition, tests of BD's developmental effects have focused on death of the developing organism, structural abnormalities, and in utero growth retardation; functional deficiencies in postnatal capability, (e.g. in the central nervous system or lung), have not been sought. (See Exs. 23–73, 23–76 for a description of postnatal effects and reproductive risks.)

In this risk assessment for BD, OSHA has relied primarily on a method employing a margin of safety approach to estimate the risks of reproductive hazards. Although the use of margins of safety is a generally accepted methodology (Exs. 23–72, 23–74, 23–75), OSHA has often relied on a more quantitative approach to risk assessment in order to establish significant risks. To date, only a few attempts have been made to develop methodology to quantitatively assess the risks associated with reproductive and developmental hazards. Therefore, OSHA is currently searching for methods to better quantify these risks and the Agency welcomes any information with respect to this issue.

VII. Significance of Risk

OSHA's overall analytic approach for setting worker health standards is a four-step process consistent with recent court interpretations of the OSH Act and a rational objective policy formulation. In the first step, quantitative risk assessments are performed where possible and considered with other relevant factors to determine whether the substance to be regulated poses a significant risk to workers. In the second step, OSHA considers which, if any, of the proposed standards being considered for the substance will substantially reduce the risk. In the third step, OSHA looks at the best available data to set the most protective exposure limit that is both technologically and economically feasible. In the fourth and final step, OSHA considers the most cost-effective way to achieve the objective.

In the Benzene decision, the Supreme Court indicated when a reasonable person might well consider the risk significant and take steps to decrease it. The Court stated:

> It is the Agency's responsibility to determine in the first instance what it considers to be a "significant" risk. Some risks are plainly acceptable and others are plainly unacceptable. If for example, the odds are one in a billion that a person will die from cancer by taking a drink of chlorinated water, the risk clearly could not be considered significant. On the other hand, if the odds are one in a thousand that regular inhalation of gasoline vapors that are 2% benzene will be fatal, a reasonable person might well consider the risk significant and take the appropriate steps to decrease or eliminate it. *(I.V.D. v. A.P.I.,* 448 U.S. at 655).

The Supreme Court's language indicates that the examples given were of excess risk over a lifetime. It speaks of "regular inhalation" which implies that it takes place over a substantial period of time and refers to the "odds * * * that a person will die," obviously a once in a lifetime occurrence.

The Court indicated, however, that the significant risk determination required by the OSH Act is "not a mathematical straitjacket" and that "OSHA is not required to support its findings with anything approaching scientific certainty." The Court ruled that "a reviewing court (is) to give OSHA some leeway where its findings must be made on the frontiers of scientific knowledge (and that) * * * the Agency is free to use conservative assumptions in interpreting the data with respect to carcinogens, risking error on the side of overprotection rather than underprotection" (448 U.S. at 655, 656).

As part of the overall significant risk determination, OSHA considers a number of factors. These include the type of risk presented, the quality of the underlying data, the reasonableness of the risk assessments, the statistical significance of the findings and the significance of risk (Arsenic, 48 FR 1864, January 14, 1983).

Exposure to BD can cause a number of serious health effects. As discussed above, BD exposure caused a variety of cancers in experimental animals, including hemangiosarcomas of the heart, malignant lymphomas and alveolar/bronchiolar adenomas and carcinomas. BD exposure also poses potentially adverse reproductive and developmental risks as well as the risk of anemia.

In this preamble OSHA has presented data demonstrating a dose response relationship between BD exposure and cancer in experimental animals, epidemiological evidence of increased mortality from cancers of the lymphopoietic system in humans and evidence of reproductive and developmental toxicity in animals. Unlike the data on carcinogenic and reproductive and developmental effects in experimental animals which are quantifiable, the human data and the mutagenic data are insufficient to enable OSHA to incorporate them into a quantitative risk assessment. Nevertheless, these data provide further qualitative evidence of serious adverse health effects.

Mutagenic effects have been identified in both *in vitro* and *in vivo* test systems. Evidence that BD or its metabolite possesses mutagenic activity is consistent with evidence that BD is a carcinogen. Other possible adverse effects caused by BD's ability to alter somatic and germ cells are presently unknown, and it is not possible to quantify the genetic risks attributable to BD's mutagenic activity at this time.

Clearly, the cancers associated with BD are risks of the most serious and often fatal kind. The other diseases, primarily reproductive and developmental effects, are serious and potentially fatal. Although OSHA's preliminary finding of significant risk is based on the cancer risk which the agency believes is, by itself, sufficient to show significant risk, the other risks, which cannot be quantified completely, support the finding.

As discussed above, OSHA has performed a quantitative risk assessment based on the NTP inhalation study of mice. Statistically significant elevated tumor incidence was observed in the mice at multiple sites. Overall tumor incidence exceeded 80% in all exposure groups, despite early termination of the study.

OSHA's "best" estimate of risk was derived from the female mouse heart hemangiosarcoma data using the multistage model. At the current PEL of 1,000 ppm BD, this model predicted 147 excess cancer deaths per 1,000 employees assuming such employees have regular exposure to BD for the period of a working lifetime (45 years).

This estimate of risk for BD is well in excess of the one death per thousand employees suggested by the Supreme Court in the Benzene decision as representing a "significant risk." Moreover, risk for BD at the current PEL exceeded the risk for other hazardous substances which OSHA has found to be significant in pervious rulemakings. Estimates per 1,000 employees for a working lifetime exposure were 148–425 lung cancer deaths from inorganic arsenic (48 FR 1864, 1896, January 14, 1983); 63–109 cancer deaths from ethylene oxide (49 FR 25763, June 22, 1984); 70–110 angiosarcoma cancer deaths from ethylene dibromide (48 FR 45975, October 7, 1983) and 95 leukemia deaths from exposure to benzene (52 FR 34505, September 11, 1987) based on the PELs prior to the completion of new lower standards.

While OSHA has relied on the multistage model to determine risk from exposure to BD at the current and proposed permissible exposure limits, the Agency did review the risk assessments based on other data and employing other mathematical models. Since other models calculated the risk only at 10 ppm, for the purpose of comparison, OSHA conducted another risk assessment at this 10 ppm, in addition to its best estimate of risk at 1,000 ppm. OSHA risk estimates at 10 ppm were very consistent and compatible with those estimated by other models. OSHA's best estimate of risk at 10 ppm based on the female mouse heart hemangiosarcoma data is 13 cancer deaths per 1,000 employees. In estimating risks from the pooled male mouse tumors data, Environ estimated 47 deaths per 1,000 employees at 10 ppm using a time-to-tumor model (Ex. 28–14). CAG estimated 60 deaths per 1,000 employees at 10 ppm using the pooled female rat tumor data and the one hit model (Ex. 17–21). Also at exposures of 10 ppm, OTS estimated 39 deaths per 1,000 employees using the male mouse hemangiosarcoma data and the one-hit model (Ex. 17–5).

Estimates would, of course, be much higher for exposure at the current PEL of 1,000 ppm. These risk estimates support OSHA's preliminary determination that significant risks exist from exposure to BD at the current PEL.

Public response to the ANPR indicates agreement that the current permissible exposure limit is too high. What remains at issue is how low the PEL should be, with industry sources favoring 10 ppm, and employees and their representatives favoring 1 ppm. Many industries have already voluntarily established limits well below 1,000 ppm, and some industries are below the 10 ppm recommended by ACGIH in 1983. OSHA believes that these voluntary reductions may, in part, reflect concern of management that workers exposed to BD at the current PEL are at risk of adverse health effects.

In short, OSHA's preliminary risk estimates from BD are similar to other risks which OSHA has concluded are significant and are substantially higher than the example presented by the Supreme Court. Moreover, the risk estimates are well supported by quantitative and qualitative data. Consequently, OSHA concludes that the risk estimate of 147 deaths per 1,000 employees is clearly significant and preliminarily concludes that BD presents a significant risk at 1,000 ppm.

OSHA's best estimate of cancer risk at the proposed PEL of 2 ppm is 5 per 1,000 employees for 45 years of exposure. The Agency's own analyses, however, have produced estimates of risk which range from .2 per 1,000 to 18 per 1,000 at this exposure level. Any of these estimates is statistically plausible, but as discussed in the Preliminary Quantitative Risk Assessment section of this preamble, the uncertainty associated with any of these estimates is greater than the uncertainty associated with the estimate derived from the female mouse heart hemangiosarcoma data. The estimate of risk at 2 ppm derived from the two-stage model fit to the pooled female rat tumor data is 3 per 1,000, but the two-stage model gives a very poor fit to these data. When the high dose group is dropped and a one-hit model fit to the data, the estimate of risk at 2 ppm increases to 12 per 1,000 but this estimate does not rely on all the available data. When the mammary fibroadenoma incidence rates are excluded from the pooled female rat tumor data, the multistage model gives an estimate of risk of 1 per 1,000 at 2 ppm, but here again, important information is excluded. As discussed in the carcinogenic health effects section of this preamble, many experts believe that mammary fibroadenomas represent a carcinogenic response, and the observation of an increase in the number of tumors per tumor bearing rat provides additional evidence of the carcinogenic potency of BD. The pooled female mouse tumor data give the lowest estimate of risk at 2 ppm when fit to a two-stage model, .2 per 1,000, but until the relevance of lymphomas in the mouse is determined, the meaning of this risk estimate is unclear. OSHA's best estimate of cancer risk is based on the female mouse heart hemangiosarcoma data because these tumors are so rare there can be little doubt that they are due to anything but BD exposure. Yet, in basing its best estimate on these data the Agency is excluding other tumor incidence data, and this contributes to the uncertainty of OSHA's estimate.

OSHA believes that the cancer risk of exposures at the proposed exposure limit of 2 ppm will be significant. In addition, estimates of risk of reproductive and developmental toxicity indicate that there may still be significant risks of these adverse effects at the proposed 2 ppm limit.

Guidance for the Agency in evaluating significant risk is provided by an examination of occupational risk rates and legislative intent. For example, in the high risk occupations of fire fighting, and mining and quarrying, the average risk of death from occupational injury or an acute occupationally related illness from a lifetime of employment (45 years) is 27.45 and 20.16 per 1,000 employees, respectively. Typical risks in occupations of average risk are 2.7 per 1,000 for all manufacturing and 1.62 per 1,000 for all service employment. Typical risks in occupations of relatively low risk are 0.48 per 1,000 in electric equipment and 0.07 per 1,000 in retail clothing. These rates are derived from 1979 and 1980 Bureau of Labor Statistics (BLS) data from employers with 11 or more employees adjusted for 45 years of employment for 48 weeks per year. These rates include only fatalities from cases reportable to BLS and generally exclude deaths from chronic exposure to chemicals.

There are relatively few data on risk rates for occupational cancer as distinguished from occupational injury and acute illness. The estimated cancer fatality rate from the maximum permissible occupational exposure to ionizing radiation is 17 to 29 per 1,000. (47 years at 5 rems; Committee on the Biological Effects of Ionizing Radiation (BEIR) III predictions.) However, most radiation standards require that exposure limits be reduced to the lowest level reasonably achievable below the exposure (the ALARA principle). Approximately 95% of radiation workers have exposures less than one-tenth the maximum permitted level. The risk at one-tenth the permitted level is 1.7 to 2.9 per 1,000 exposed employees * * * (BEIR I estimates are 30 to 60 per 1,000 at 5 rem per year and 3 to 6 per 1,000 at one-tenth that level.)

Congress passed the Occupational Safety and Health Act of 1970 because of a determination that occupational safety and health risks were too high. Based on this, it is clear that Congress gave OSHA authority to reduce risks of average or above average magnitude when feasible. OSHA believes that the proposed standard for BD will reduce risk from OSHA's best estimate of 147 per thousand at the current PEL to below OSHA's best estimate of 5 per thousand, and, therefore, the Agency is carrying out the Congressional intent within the limits of feasibility and is not attempting to reduce insignificant risks.

OSHA has determined that the existing standard for BD poses significant risk of cancer to employees. Even under current exposure conditions which the Agency estimates are well below the current PEL, OSHA's best estimate of cancer deaths due to occupational exposure to BD is in excess of 25 among the 5700 workers in the crude, monomer, and polymer production sectors of the industry (see the Summary of Preliminary Regulatory Impact and Regulatory Flexibility

Analysis section of this preamble for details). For BD, the proposed TWA concentration limit would be set at the lowest feasible limit because there is still a residual risk of developing cancer from exposure to BD despite a 500-fold reduction in permissible exposure. After implementing controls to comply with the 2 ppm proposed PEL, OSHA's best estimate of cancer deaths due to occupational BD exposure is in excess of 3 among the 5700 affected workers. Because of the feasibility limitations, OSHA integrated other protective provisions into the proposed standard to further reduce the risk of developing cancer among employees exposed to BD. Employees exposed to BD at the proposed TWA concentration limit without the supplementary provisions would remain at risk of developing adverse health effects, so that inclusion of other protective provisions, such as medical surveillance and employee training, is both necessary and appropriate. The inclusion of these supplementary provisions would reduce the residual risks for workers. Although the additional reduction in risk is not quantifiable, OSHA believes it is reasonable to assume that the revised TWA exposure limit coupled with the STEL and associated ancillary provisions, substantially reduces residual significant risk.

Under both the Congressional intent and the Supreme Court rationale, OSHA must, if feasible, seek to reduce risks below those estimated by the risk assessments to persist at a PEL of 2 ppm. However, OSHA expects that the proposed rule as drafted will reduce the risks of BD below those estimated using the mathematical model. The estimates of risk consider only exposures at the PEL, and do not fully take into account the other protective provisions of the proposed standard such as medical surveillance. The decrease in risk to be achieved by additional provisions cannot be adequately quantified beyond a determination that they will add to the protection provided by the lower PEL alone. OSHA has determined that employers who fulfill the provisions of the standard as proposed will provide protection for their employees from the hazards presented by occupational exposure to BD well beyond those which would be indicated solely by reduction of the PEL.

In determining the level to which the permissible exposure limit should be lowered, several alternative 8-hour limits and excursion limits were considered. Specifically, OSHA considered 8-hour TWAs of 10 ppm, 5 ppm, 2 ppm, and 1 ppm, with corresponding STELs of 50 ppm, 25 ppm, 10 ppm, and 5 ppm. OSHA believes that compliance with an 8-hour TWA of 2 ppm coupled with a STEL of 10 ppm is technologically and economically feasible at this time based on data indicating that several industries or industry segments are presently controlling exposures to or very near this level. Regarding the feasibility of compliance with a PEL of 1 ppm, however, OSHA's current data indicate such compliance is infeasible since available technology that is already in place could not achieve the PEL of 1 ppm. In those operations employing modern and available technology 1 ppm could not be achieved due to intermittent releases and not continuous sources. The current technology employs closed systems. OSHA's preliminary analysis of technological and economic feasibility of the proposal is discussed in the following section of the preamble.

VIII. Engineering Controls To Reduce Worker Exposures

Since the feasibility of engineering controls depends heavily on the chemical and physical characteristics of the substance, as well as production or process technologies, the following information has been used by OSHA for its feasibility assessment.

BD is a flammable gas at atmospheric pressure and temperature, therefore it is always handled in closed systems with precautions taken to minimize leaks. At 25 °C it can be liquefied at a pressure of 25 psig. It is produced and consumed under pressure, stored and transported as a liquid. Process equipment is opened only for maintenance and product sampling. Because equipment for monomer production, storage tanks, loading and unloading equipment, some polymerization reactors, and monomer recovery equipment are located outdoors, leaks and other emissions are diluted and dispersed in the atmosphere and thus the exposure of workers to BD are minimized or avoided (Ex. 3–21). For example, in the case of monomer production, the processes are highly automated using the enclosed system, and operators monitor them from control rooms, spending little time in the actual process areas.

Workers are exposed to BD when loading and unloading monomer; taking samples and handling samples in laboratories; exposing leaks from processing equipment piping, and pumps; opening up equipment and lines for maintenance work; and venting waste and noncondensible gases from processes. The use of engineering controls to minimize these leaks are discussed below.

Most crude BD and monomer is transported by pipeline, but plants remote from the petrochemical producers receive BD by barges, rail tank cars or tank trucks (Ex. 3–21). In pipeline transfer, the BD is totally enclosed, eliminating loading/unloading exposure problems. But with other methods of transport (e.g. tank cars), operators are potentially exposed while coupling and uncoupling hoses and gauging tank levels. Exposures during connecting and disconnecting transfer lines can be minimized by purging them with nitrogen and venting to a flare. Frequently slip-tube gauges are used to monitor tank levels. A slip-tube gauge releases a plume of BD to the air when the level reaches a predetermined point, thus sending a signal to the operator and eliminating the need to stand close to the tank as it empties. Magnetic gauges, operating without release of vapor to the air, are an improvement over slip-tube gauges (Ex. 16–29).

Sampling for quality control is another source of exposure to BD workers. Quality control samples are sometimes manually taken in cylindrical containers called bombs. The bomb is connected by tubing to a sample port, BD is allowed to flow through it and displace (purge) the air or inert gas within it, then valves at both ends of the bomb are closed, and the bomb is disconnected from the sampling line and sent to the quality control laboratory. Manual sampling using bombs subjects technicians to excessive BD exposure, especially during the purging process, where the process fluid is allowed to escape through the bomb to the other end through to atmosphere. Various methods for reducing or eliminating this exposure have been devised. In some instances it has been proven to be feasible to use on-line gas chromatographs to replace manual sampling operations. In closed-loop sampling, the outlet end of the bomb is connected to a production/process line at lower pressure than the sample port. When the valves are opened, process fluid flows through the bomb into the low pressure line. The only vapors escaping are those in the cavity of open ends of the lines when the bomb is disconnected. This hookup can be refined further by piping inert gas into the sampling circuit in a fashion to permit purging BD from the line cavities after the valves to the sample bomb have been closed (Ex. 16–29). Placing the sampling port in an enclosure or fuming exhausted cupboard to a venting or flare system is another measure that can be taken (Ex. 16–29). Closed-loop sampling requires a downstream line, not always available, at lower pressure than the

upstream sampling line, into which the purge line can be run. Such a lower pressure line can be provided by running a collection line to a flare or vent line. Pumps mounted downstream from the sampling bomb is another method for purging. Handling of samples in the laboratory may expose laboratory personnel to BD. Gas released from the bombs for passage through analytical equipment should be exhausted within hoods. Purging of the bombs, if done in the laboratory, should be conducted in hoods.

Various types of equipment releases BD into the working environment. Examples are leaks from flanges on towers, piping, reactors, and heat exchangers, from seals on pump, compressor and agitator shafts, through imperfectly seated relief valves, from drain valves and then associated end caps, and from valve stems. A number of methods for minimizing some types of leaks, or their effects, can be adopted. One control practice is to regularly inspect equipment and lines where leaks may occur and have the necessary maintenance work performed promptly. Restricting access to areas where leaks are likely is a complementary practice. Continuous monitoring with an alarm system to alert workers of leak occurrence would definitely lessen the extent and the magnitude of workers, exposure, if maintenance or repair work is performed promptly.

The problem of leaks due to the imperfect sealing of relief valves is sometimes resolved by installing rupture disks upstream from the valves. Occasionally it is practical to stop leaks through valves on lines opening into the work area by capping the open ends of the lines.

Many process vessels and storage tanks and the final stages of recovery or stripping processes have to be vented periodically or continuously to remove non-condensible gases. Sometimes vent streams are passed through solvent recovery operations to recover BD but other times they are vented directly to the atmosphere or flared.

Leaks from pumps, compressors and polymerizer agitators are common sources of employees' exposure. BD escapes around the rotating drive shaft. The simplest type of seal involves compressing packing in a stuffing box around the shaft in the opening to the pump or vessel. When the pumped fluid is free of particulates, as is the case for BD, mechanical seals can be used; the seal consists of two precisely finished annular metal faces pressing against each other, the faces perpendicular to the shaft. One face rotates with the shaft; the other is fixed. Pressure from the fluid in the pump plus spring pressure press them together. Better seals may be obtained with the mechanical seals than with packing. Double or tandem seals consists of two mechanical seals mounted close together on the shaft and contained in an enclosing structure which may be part of the pump casing. A seal liquid, usually oil, is circulated through the cavity between the seals. If the seal liquid is maintained at a higher pressure than the product stream, possible seal failure can be detected by a drop in the pressure of the seal liquid system. In an alternative scheme the seal liquid is run at lower pressure than the fluid being pumped, escaping fluid from the pump mixes or dissolves in the seal liquid and is vented under control from the seal liquid circulating system (Ex. 17–18). Mechanical seals are generally used on both pumps and agitators. More complex seals may be required for compressors.

In some instances, inside buildings for example, local exhaust ventilation may be used to capture the escaped vapors from pump and agitator shafts into the work area. Equipment which must be opened frequently for maintenance may be purged with inert gas, steam or water to flush out BD before it is opened.

IX. Summary of Preliminary Regulatory Impact and Regulatory Flexibility Analysis

A. Introduction

BD is a high-volume chemical used primarily in the manufacture of synthetic rubbers via polymerization. Although there are three commercial processes available to produce BD, today virtually all BD is produced by the ethylene co-product method. In the ethylene co-product method, BD monomer is produced by a two-stage process: (1) Production of the C_4 co-product during the manufacture of ethylene; and, (2) the recovery of BD from the C_4 co-product. Since virtually all domestically produced BD is manufactured by the ethylene co-product method, these two stages were used to classify the operations in the industry. Activities that solely produce the C_4 co-product were classified as Crude BD operations. Activities that recover BD from the C_4 co-product were classified as BD Monomer operations. Finally, activities that use BD to produce synthetic rubber via polymerization were classified as BD Polymer operations.

B. Industry and Exposure Profile

The rising price of natural gas during the 1970s caused ethylene producers to switch to the use of heavier, less expensive feedstocks. The use of these heavier feedstocks, which require greater severity in the cracking process, increased the BD concentration in the co-product streams. Today typical C_4 co-product streams of ethylene product are composed of about 40 percent BD (Ex. 30).

According to CMA, there are 30 facilities, operated by 20 firms, that produce crude BD (Ex. 28–14). JACA reports that one of these facilities, is no longer in operation (Ex. 30). Of the 29 facilities in operation, 19 are classified as crude BD producers. The remaining 10 facilities also recover BD and are also classified as BD monomer producers.

The crude producers employ approximately 580 workers with potential BD exposures and have an estimated annual capacity of crude BD (i.e., contained in the C_4 co-product stream) of 847 million pounds (Ex. 30). Table 23 provides a snapshot estimate of the number of workers exposed in each job category over various ranges of exposure within the crude BD industry. For example, in the case of tank farm technicians, on an average day an estimated 25 of 29 workers are exposed to less than 2 ppm.

TABLE 23.—CURRENT EXPOSURE PROFILE—CRUDE BD PRODUCTION [1]

Occupational group	Numerical and percentage distribution of workers by concentration range (ppm)							
	<2[2]	<1	1-<2	2–2	2.5–2.5	5-<10	>10	Total
Process technician:								
Tank farm	25	23	2	1	1	0	2	29
	86%	78%	8%	3%	3%	0%	8%	100%
Pump alley	176	139	37	9	23	12	12	232
	76%	60%	16%	4%	10%	5%	5%	100%
Control room	80	76	4	1	3	2	1	87

TABLE 23.—CURRENT EXPOSURE PROFILE—CRUDE BD PRODUCTION [1]—Continued

Occupational group	Numerical and percentage distribution of workers by concentration range (ppm)							
	<2[2]	<1	1-<2	2-2	2.5-2.5	5-<10	>10	Total
	93%	88%	5%	1%	3%	2%	1%	100%
Lab technician:								
Analysis	49	42	7	2	4	2	1	58
	84%	72%	12%	4%	7%	4%	1%	100%
Cylinder voiding	17	13	4	1	5	5	30	58
	30%	23%	7%	2%	8%	8%	52%	99%
Other:								
Maintenance	106	99	7	2	4	2	2	116
	91%	85%	6%	2%	3%	2%	2%	100%
Total	453	392	61	16	40	23	48	580
	79%	68%	11%	2%	7%	4%	8%	100%

Source: JACA Corporation (Ex. 30).

[1] This is the estimated number of workers in each exposure grouping during any one day. Because of the variation of exposures, individual employees may fall in different exposure groupings on different days.

[2] This column is the extent of workers' exposure below OSHA proposed PEL of 2 ppm.

According to CMA there are 12 facilities, operated by 10 companies, that produce refined (99% pure) BD. These facilities have a combined annual capacity of 3,585 million pounds of refined BD. Ten of these facilities are also capable of producing crude BD and have a combined annual capacity of 1,720 million pounds of crude BD (Ex. 28–14), of the BD monomer capacity, i.e., 3,065 million pounds, recover the BD from the C_4 co-product stream either through extractive distillation or through solvent extraction. The remaining one facility, with an annual capacity of 520 million pounds, produces BD from the dehydrogenation process. The BD monomer producers employ approximately 550 workers with potential BD exposures (Ex. 30). An estimate of the number of workers exposed on a given day over various ranges in the monomer sector is presented by job category in Table 24.

TABLE 24.—CURRENT EXPOSURE PROFILE—BD MONOMER PRODUCTION [1]

Occupational group	Numerical and percentage distribution of workers by concentration range (ppm)							
	<2[2]	<1	1-<2	2-<2.5	2.5-<5	5-<10	>10	Total
Process technician:								
Railcar	33	26	7	2	5	5	7	52
	63%	50%	13%	4%	10%	9%	14%	100%
Tank truck	5	4	1	0	1	1	1	8
	63%	50%	13%	4%	10%	9%	14%	100%
Tank farm	31	28	3	1	1	0	3	36
	86%	78%	8%	2%	3%	1%	8%	100%
Pump alley	126	99	27	7	17	8	8	166
	76%	60%	16%	4%	10%	5%	5%	100%
Control room	43	41	2	1	1	1	1	47
	92%	88%	4%	2%	2%	2%	2%	100%
Lab. technician:								
Analysis	31	26	5	1	3	1	0	36
	86%	73%	13%	3%	7%	3%	1%	100%
Cylinder voiding	10	8	2	1	3	3	19	36
	28%	22%	6%	3%	8%	8%	53%	100%
Other:								
Maintenance	159	148	11	3	6	3	3	174
	91%	85%	6%	2%	3%	2%	2%	100%
Total	438	380	58	16	37	22	42	555
	80%	69%	10%	3%	7%	4%	7%	100%

Source: JACA Corporation (Ex. 30).

[1] This is the estimated number of workers in each exposure grouping during any one day. Because of the variation of exposures, individual employees may fall in different exposure groupings on different days.

[2] This column is the extent of workers' exposure below OSHA proposed PEL of 2 ppm.

The chief use of BD monomer is in the production of polymers. More than half of the BD produced is used in the manufacture of styrene-BD rubber and poly-BD rubber. (See JACA for a detailed breakdown of 1986 BD consumption.) The BD-based polymers are used in-turn to produce a broad range of end products, of which tire and rubber products represent the largest fraction (Ex. 30).

There are several processes for producing BD-based polymers, but they are all similar in terms of the basic steps in which BD is received, processed and recovered. Although Multinational Business Services in its report to OSHA (Ex. 29–6) stressed the diversity of individual polymer plants, they provided no assessment of the various controls and processes. This analysis, therefore, treats the BD polymer industry as a homogeneous sector in terms of exposures and the applicability of specific control measures.

According to JACA there are 54 process units using BD to process polymers and other miscellaneous chemicals. While some facilities contain

more than one of these process units, for the purposes of this analysis each process unit is treated as a separate facility. Thus, economies of scale arising from the joint hazard abatement by several process units located at the same facility are not discussed.

The BD polymer producers employ approximately 4,554 workers with potential BD exposures (Ex. 30). An estimate of the number of workers exposed on a given day over various ranges in the BD polymer industry is presented by job category in Table 25.

TABLE 25.—CURRENT EXPOSURE PROFILE—BD POLYMER AND MISCELLANEOUS CHEMICAL PRODUCTION[1]

Occupational group	Numerical and percentage distribution of workers by concentration range (ppm)							
	<2[2]	<1	1-<2	2-<2.5	2.5-<5	5-<10	>10	Total
Process technician:								
Unloading	15	12	3	1	2	2	3	23
	63%	50%	13%	4%	10%	9%	14%	100%
Tank Farm	190	168	22	7	14	9	4	224
	85%	75%	10%	3%	6%	4%	2%	100%
Purification	63	25	38	32	172	229	140	636
	10%	4%	6%	5%	27%	36%	22%	100%
Polymerization or Reaction	554	532	22	6	6	6		572
	97%	93%	4%	1%	1%	1%	0%	100%
Solution or Coagulation	277	277						277
	100%	100%	0%	0%	0%	0%	0%	100%
Crumbling and Drying	133	133						133
	100%	100%	0%	0%	0%	0%	0%	100%
Control Room	271	268	3					271
	100%	99%	1%	0%	0%	0%	0%	100%
Packaging	381	377	4					381
	100%	99%	1%	0%	0%	0%	0%	100%
Warehousing	192	190	2					192
	100%	99%	1%	0%	0%	0%	0%	100%
Lab. technician:								
Analysis	369	334	35	9	26	18	18	440
	84%	76%	8%	2%	6%	4%	4%	100%
Other:								
Maintenance	1248	1166	82	27	42	27	27	1371
	91%	85%	6%	2%	3%	2%	2%	100%
Utilities	33	32	1	0	1			34
	96%	93%	3%	1%	3%	0%	0%	100%
Total	3726	3514	212	82	263	291	192	4554
	82%	77%	5%	2%	6%	6%	4%	100%

Source: JACA Corporation (Ex. 30).

[1] This is the estimated number of workers in each exposure grouping during any one day. Because of the variation of exposures, individual employees may fall in different groupings on different days.

[2] This column is the extent of workers' exposure below OSHA proposed PEL of 2 ppm.

C. Technological Feasibility

Four regulatory alternatives were considered to reduce occupational exposure to BD in these three industries: (1) The combination of a permissible exposure limit (PEL) of 10 parts per million (ppm) as an 8-hour time weighted average (TWA) and a short-term exposure limit (STEL) of 50 ppm as a 15-minute TWA, (2) the combination of a 5 ppm PEL and a 25 ppm STEL, (3) the combination of a 2 ppm PEL and a 10 ppm STEL, and, (4) the combination of a 1 ppm PEL and a 5 ppm STEL. Based upon its analysis of the alternatives, OSHA has preliminarily determined that compliance with the first three alternatives is technologically feasible primarily through the use of engineering and work practice controls although under each of these alternatives some additional respirator use will be necessary to protect some workers in difficult to control situations. The analysis also shows that compliance with the combination of a 1 ppm PEL and a 5 ppm STEL may not be technologically feasible without the extensive use of respiratory protection. OSHA's analysis is in relative agreement with the report of Heiden and Associates for the Chemical Manufacturers Association, which indicated that a PEL of 10 ppm was technologically feasible through the use of engineering controls and work practices. Heiden also found that a PEL of 1 ppm was infeasible without extensive and routine use of respirators [Ex. 28–14].

OSHA's feasibility analysis is primarily based upon the work of PEI Associates as presented in the JACA report (Ex. 30). PEI has extensive experience in monitoring BD exposures and evaluating BD control technology. This experience, which includes conducting several walk through surveys of facilities (in the crude, monomer and polymer sectors) for EPA and NIOSH and developing several reports on the subject (Exs. 17–16, 17–18 & 17–34), has allowed PEI to compile an extensive data base for the assessment of occupational exposures to BD.

Based upon these data, JACA recommended methods for meeting each of the regulatory alternatives. These recommendations are not a comprehensive guide on how specific plants could be brought into compliance with each regulatory alternative because there are minor differences among the facilities in each sector. Instead, this section is intended to illustrate the general techniques that could be utilized by a typical or "model" plant in each sector to meet the requirements of each alternative.

Both the crude BD and BD monomer production processes occur in closed systems and are highly automated. Operators are not routinely required to spend much time in the processing area and have relatively nominal exposures. Nonetheless, according to JACA, the following three operational categories present a serious potential for occupational exposure to BD:

1. Decontamination and maintenance of process equipment;
2. Sampling, handling, and analysis of quality control samples; and,
3. Loading and unloading of crude and refined BD.

The JACA report includes a detailed description of these operations.

There are three basic methods for processing BD into polymers (i.e., emulsion polymerization, solution polymerization and liquid or vapor phase reactions). These processes are similar in that they usually contain several of the following operations:

1. Unloading and storage of BD monomer;
2. Pre-treatment of the monomer to remove inhibitors or water;
3. Purification or recovery of excess unreacted monomer for recycling into to the process;
4. Post-treatment of the BD polymer to stabilize and purify the product; and,
5. Packaging of the final product for shipment. (Ex. 30)

A comparison of these operations with those of the crude BD and BD monomer facilities reveals several similarities. For example, both types of facilities use and have many of the same sources of potentially significant occupational exposure to BD (e.g. decontamination and maintenance of process equipment; sampling; handling, and analysis of quality control samples; and, loading and unloading of BD). However, since the BD polymer facilities have several types of operations that are not present at the crude BD and BD monomer facilities, they also have additional areas where there is a potential for excessive occupational exposure to BD, including the polymerization, reaction, purification, finishing, and packaging areas (Ex. 30).

According to JACA, it would be very difficult to achieve the 1 ppm PEL/5 ppm STEL regulatory alternative primarily through the use of engineering and work practice controls. Such an alternative could only be met through the extensive and routine use of respirators. This position is also supported by the Heiden analysis of the monomer sector (Ex. 28–14). Thus, OSHA preliminarily concludes that it may not be feasible to achieve the 1 ppm PEL/5 ppm STEL regulatory alternative solely through engineering and work practice controls.

Based upon the JACA analysis, OSHA further concludes that the 10 ppm PEL/50 ppm STEL, the 5 ppm PEL/25 ppm STEL, and the 2 ppm PEL/10 ppm STEL are achievable primarily through the use of engineering and work practice controls, although some supplemental respiratory use may also be required during certain tasks. Tables 26 through 28 list these regulatory alternatives along with PEI's determinations of how each job category in each industry sector can meet these alternatives.

TABLE 26.—INCREMENTAL CONTROL REQUIREMENTS TO MEET THE 10 PPM PEL AND 50 PPM STEL REGULATORY ALTERNATIVE

[By industry sector, by classification]

Job category	Control requirements
Crude and Monomer Productions	
Process technicians:	
Railcar (monomer only)	Magnetic gauges.
Tank truck (monomer only)	Current controls are sufficient.
Tank farm	Closed-loop sampling devices.
Pump alley	Closed-loop sampling devices.
Control room	Current controls are sufficient.
Laboratory technicians:	
Analysis	Improved hoods & general ventilation.
Cylinder voiding	Vacuum exhaust ventilation or improved lab hoods.
Others:	
Maintenance	Current controls are sufficient.
Polymer Production	
Process technicians:	
Unloading	Magnetic gauges.
Tank farm	Closed-loop sampling devices.
Purification	Closed-loop sampling devices & respirators for 25% of workers.
Polymerization or reaction	Current controls are sufficient.
Solution or coagulation	Current controls are sufficient.
Crumbling and drying	Current controls are sufficient.
Control room	Current controls are sufficient.
Packaging	Current controls are sufficient.
Warehousing	Current controls are sufficient.
Laboratory technicians:	
Analysis	Vacuum exhaust, general ventilation, and improved laboratory hoods.
Others:	
Maintenance	Current controls are sufficient.
Utilities	Current controls are sufficient.

Source: JACA Corporation (Ex. 30)

TABLE 27.—INCREMENTAL CONTROL REQUIREMENTS TO MEET THE 5 PPM PEL AND 25 PPM STEL REGULATORY ALTERNATIVE

[By industry sector, by job classification]

Job category	Control requirements
Crude and Monomer Productions	
Process technicians:	
Railcar (monomer only)	Same controls as previous alternative.
Tank truck (monomer only)	Some respirator use for all workers.

TABLE 27.—INCREMENTAL CONTROL REQUIREMENTS TO MEET THE 5 PPM PEL AND 25 PPM STEL REGULATORY ALTERNATIVE—Continued

[By industry sector, by job classification]

Job category	Control requirements
Tank farm	Some respirator use for all workers.
Pump alley	Some respirator use for 25% of workers.
Control room	Current controls are sufficient.
Laboratory technicians:	
Analysis	Same controls as previous alternative.
Cylinder voiding	Some respirator use for all workers.
Others:	
Maintenance	Current controls are sufficient.
Polymer Production	
Process technicians:	
Unloading	Same controls as previous alternative.
Tank farm	Same controls as previous alternative.
Purification	Same controls (including respirators) as the previous alternative.
Polymerization or reaction	Current controls are sufficient.
Solution or coagulation	Current controls are sufficient.
Crumbling and drying	Current controls are sufficient.
Control room	Current controls are sufficient.
Packaging	Current controls are sufficient.
Warehousing	Current controls are sufficient.
Laboratory technicians:	
Analysis	Same controls as previous alternative.
Others:	
Maintenance	Current controls are sufficient.
Utilities	Current controls are sufficient.

Source: JACA Corporation (Ex. 30)

TABLE 28.—INCREMENTAL CONTROL REQUIREMENTS TO MEET THE 2 PPM PEL AND 10 PPM STEL REGULATORY ALTERNATIVE

[By industry sector, by job classification]

Job category	Control requirements
Crude and Monomer Productions	
Process technicians:	
Railcar (monomer only)	Some respirator use for all workers.
Tank truck (monomer only)	Some respirator use for all workers.
Tank farm	Some respirator use for all workers.
Pump alley	Some respirator use for 25% of workers.
Control room	Some respirator use for 25% of workers.
Laboratory technicians:	
Analysis	Some respirator use for all workers.
Cylinder voiding	Some respirator use for all workers.
Others:	
Maintenance	Some respirator use for 10% of workers.
Polymer Production	
Process technicians:	
Unloading	Some respirator use for all workers.
Tank farm	Some respirator use for all workers.
Purification	Some Full-face air-Purifying respirator. Use for 25% of workers.
Polymerization or reaction	Current controls are sufficient.
Solution or coagulation	Current controls are sufficient.
Crumbling and drying	Current controls are sufficient.
Control room	Current controls are sufficient.
Packaging	Current controls are sufficient.
Warehousing	Current controls are sufficient.
Laboratory technicians:	
Analysis	Some respirator use for 50% of workers.
Others:	
Maintenance	Some respirator use for 10% of workers.
Utilities	Current controls are sufficient.

Source: JACA Corporation (Ex. 30)

As an important component of engineering controls, JACA assumed that leak detection and repair programs, which require periodic monitoring using an organic vapor analyzer (as well as a strip chart recorder and a gas chromatograph), would be used by all facilities to meet the 5 ppm PEL/25 ppm STEL and 2 ppm PEL/10 ppm STEL regulatory alternatives. Thus, JACA concluded that most of the potentially hazardous occupational exposures from

leaks that emanate from pumps and compressors would be detected before any substantial amounts of BD accumulates. It may be the case, however, that in some circumstances, continuous monitoring with an alarm system might be a more effective means to control worker exposures. OSHA believes that continuous monitoring would alert employers and employees to leaks instantaneously, and consequently appropriate action would be undertaken without undue delay. JACA did not consider the technological or economic feasibility of this particular control, and OSHA solicits comments on its appropriateness in the industries that will be affected by this standard.

JACA does not foresee the immediate need for an extensive replacement or retrofitting of existing pumps and compressors with dual mechanical seals because workers typically spend the majority of the day away from this equipment. Thus, JACA believes that dual mechanical seals—while an effective environmental control—would, under the present set of circumstances, have little effect on occupational exposures.

An examination of Tables 26 through 28 reveals that JACA recommended some additional respirator use for all three regulatory alternatives. For the 10 ppm PEL/50 ppm STEL alternative, additional respirators will be required only in the BD polymer sector and not in the crude BD and BD monomer sectors. For the 5 ppm PEL/25 ppm STEL and the 2 ppm/10 ppm STEL, additional respirator use will be required in all three sectors. In general, JACA recommended that respirators be used during operations such as sample collection, cylinder voiding, loading and unloading, and maintenance.

JACA determined that the majority of workers will be protected without the use of respirators under all three alternatives. Moreover, since no worker would be required to wear a respirator for an entire 8-hour shift and since only a fraction of the workers in some job categories may routinely need to use respirators, OSHA estimated the percentage of a typical work day that engineering and work practice controls would provide sufficient protection for workers under PELs of 10 ppm, 5 ppm, and 2 ppm. These estimates are presented in Table 29 and show the amount of time that respirator use is required in order to meet a given PEL. Another way to conceptualize the data presented in Table 28 involves the notion of "full time equivalent workers" requiring respirator protection. Since no worker would be required to wear respirators for an entire 8-hour shift, the number of full time equivalent workers required to use respirators is estimated by multiplying the number of workers required to wear respirators by the portion of their typical work-day that would be spent in respirators. For example, if four workers were required to wear a respirator 25 percent of each day, then this would be equivalent to one full time respirator user. Table 30 shows that in no specific job category does the number of full-time equivalent workers in respirators exceed 50 percent of the number of workers. In fact, under the proposed 2 ppm PEL regulatory alternative the number of full-time equivalent workers in respirators is less than 15 percent of the exposed work force in each of the three industry sectors.

TABLE 29.—1,3-BUTADIENE RESPIRATOR USE—PROJECTED NUMBER OF WORKERS AND TIME IN RESPIRATORS UNDER VARIOUS PELs" [1]

[By industry sector, by job classification]

Job category [2]	Total emply	Respirator usage under the following PELs-					
		PEL = 10 ppm		PEL = 5 ppm		PEL = 2 ppm	
		Number of Wkrs.	(Percent of time)	Number of Wkrs.	(Percent of time)	Number of Wkrs.	(Percent of time)
Crude Production							
Process technicians:							
Tank farm	29	0	(0.0%)	29	(17.5%)	29	(17.5%)
Pump alley	232	0	(0.0%)	58	(17.5%)	58	(17.5%)
Control room	87	0	(0.0%)	0	(0.0%)	22	(37.5%)
Laboratory technicians:							
Analysis	58	0	(0.0%)	0	(0.0%)	58	(25.0%)
Cylinder voiding	58	0	(0.0%)	58	(37.5%)	58	(37.5%)
Other: Maintenance	116	0	(0.0%)	0	(0.0%)	12	(62.5%)
Sector total	580	0		145		236	
Monomer Production							
Process technicians:							
Railcar	52	0	(0.0%)	0	(0.0%)	52	(25.0%)
Tank truck	8	0	(0.0%)	8	(50.0%)	8	(50.0%)
Tank farm	36	0	(0.0%)	36	(17.5%)	36	(17.5%)
Pump alley	166	0	(0.0%)	42	(17.5%)	42	(17.5%)
Control room	47	0	(0.0%)	0	(0.0%)	12	(37.5%)
Laboratory technicians:							
Analysis	36	0	(0.0%)	0	(0.0%)	36	(25.0%)
Cylinder voiding	36	0	(0.0%)	36	(37.5%)	36	(37.5%)
Other: Maintenance	174	0	(0.0%)	0	(0.0%)	17	(62.5%)
Sector total	555	0		122		239	
Polymer and Miscellaneous Chemical Production							
Process technicians:							
Unloading	23	0	(0.0%)	0	(0.0%)	23	(25.0%)
Tank Farm	224	0	(0.0%)	0	(0.0%)	224	(17.5%)
Purification	636	159	(17.5%)	159	(17.5%)	159	(17.5%)
Polymerization or reaction	572	0	(0.0%)	0	(0.0%)	0	(0.0%)

TABLE 29.—1,3-BUTADIENE RESPIRATOR USE—PROJECTED NUMBER OF WORKERS AND TIME IN RESPIRATORS UNDER VARIOUS PELs" [1]—Continued

[By industry sector, by job classification]

Job category [2]	Total emply	Respirator usage under the following PELs-					
		PEL = 10 ppm		PEL = 5 ppm		PEL = 2 ppm	
		Number of Wkrs.	(Percent of time)	Number of Wkrs.	(Percent of time)	Number of Wkrs.	(Percent of time)
Solution or coagulation	277	0	(0.0%)	0	(0.0%)	0	(0.0%)
Crumbing and Drying	133	0	(0.0%)	0	(0.0%)	0	(0.0%)
Control room	271	0	(0.0%)	0	(0.0%)	0	(0.0%)
Packaging	381	0	(0.0%)	0	(0.0%)	0	(0.0%)
Warehousing	192	0	(0.0%)	0	(0.0%)	0	(0.0%)
Laboratory Technician:Analysis	440	0	(0.0%)	0	(0.0%)	220	(25.0%)
Other:							
Maintenance	1,371	0	(0.0%)	0	(0.0%)	137	(62.5%)
Utilities	34	0	(0.0%)	0	(0.0%)	0	(0.0)
Sector total	4,554	159		159		763	
Total	5,689	159		426		1,238	

[1] Figures assume that all feasible engineering controls and work practices are in place.
[2] Note that these job categories are not consistent with those of Matanoski (Ex.9). For example, Matanoski included some tank farm workers in the "other maintenance" category, while PEI separated these two groups.
Source: Based upon PEI feasibility analysis. [2, Chapt. 3].

TABLE 30.—1,3-Butadiene Respirator Use Number of Full-Time Equivalent Workers in Respirators Under Various PELs

[By industry sector, by classification]

Job category	Number of workers	Full-time equivalent in respirators under the following PELs—		
		10 ppm	5 ppm	2 ppm
Crude Production				
Process Technicians:				
Tank farm	29	0	5	5
Pump alley	232	0	10	10
Control room	87	0	0	8
Laboratory technicians:				
Analysis	58	0	0	15
Cylinder voiding	58	0	22	22
Other: Maintenance	116	0	0	7
Sector total	580	0	37	67
Monomer Production				
Process Technicians:				
Railcar	52	0	0	13
Tank truck	8	0	4	4
Tank farm	36	0	6	6
Pump alley	166	0	7	7
Control room	47	0	0	4
Laboratory technicians:				
Analysis	36	0	0	9
Cylinder voiding	36	0	14	14
Other: Maintenance	174	0	0	11
Sector total	555	0	31	68
Polymer and Miscellaneous Chemical Production				
Process technicians:				
Unloading	23	0	0	6
Tank farm	224	0	0	39
Purification	636	28	28	28
Polymerization or reaction	572	0	0	0
Solution or coagulation	277	0	0	0
Crumbing and Drying	133	0	0	0
Control room	271	0	0	0
Packaging	381	0	0	0
Warehousing	192	0	0	0
Laboratory technicians: Analysis	440	0	0	55
Other:				
Maintenance	1371	0	0	86
Utilities	34	0	0	0
Sector total	4,554	28	28	213

TABLE 30.—1,3-Butadiene Respirator Use Number of Full-Time Equivalent Workers in Respirators Under Various PELs—Continued

[By industry sector, by classification]

Job category	Number of workers	Full-time equivalent in respirators under the following PELs—		
		10 ppm	5 ppm	2 ppm
Total	5,689	28	96	349

Source: U.S. Department of Labor, OSHA, ORA.

Based upon available data and the supporting documentation presented in the JACA report (Ex. 30), OSHA preliminarily concludes that it can not demonstrate the feasibility of achieving the 1 ppm PEL/5 ppm STEL regulatory alternative primarily through the use of engineering and work practice controls. OSHA further concludes that achievement of the 10 ppm PEL/50 ppm STEL, the 5 ppm PEL/25 ppm STEL and the 2 ppm PEL/10 ppm STEL is technologically feasible through the use of engineering and work practice controls, although some additional respirator protection use will be required. The anticipated changes in BD exposures resulting from each of the latter three feasible regulatory alternatives are presented in Table 31.

TABLE 31.—1,3-BUTADIENE EXPOSURE PROFILE—NUMBER OF WORKERS, CURRENT AND PROJECTED 8-HOUR TWA EXPOSURE MEANS UNDER VARIOUS PEL'S

[By industry sector, by job classification]

Job category	Number of workers	Projected 8-hour TWA exposure means for the following PELs—			
		10 ppm	5 ppm	2 ppm	Current exposures
Crude and Monomer Sectors					
Process technicians:					
Railcar*	52	1.16	1.16	0.24	14.64
Tank truck*	8	2.65	0.53	0.53	2.65
Tank farm	65	0.44	0.13	0.13	0.44
Pump alley	398	2.23	0.38	0.38	2.23
Control room	134	0.45	0.45	0.17	0.45
Laboratory technicians:					
Analysis	94	0.36	0.36	0.08	1.06
Cylinder voiding	94	2.42	0.48	0.48	125.32
Other: Maintenance	290	1.37	1.37	0.21	1.37
Sector total	1,135				
Polymer and Miscellaneous Chemical Production					
Process technicians:					
Unloading	23	1.16	1.16	0.24	14.64
Tank farm	224	0.46	0.46	0.10	2.08
Purification	636	0.94	0.94	0.47	7.80
Polymerization or reaction	572	0.41	0.41	0.41	0.41
Solution or coagulation	277	0.05	0.05	0.05	0.05
Crumbing and drying	133	0.03	0.03	0.03	0.03
Control room	271	0.03	0.03	0.03	0.03
Packaging	381	0.04	0.04	0.04	0.04
Warehousing	192	0.02	0.02	0.02	0.02
Laboratory technicians: Anafysis	440	0.31	0.31	0.05	2.24
Other:					
Maintenance	1,371	1.06	1.06	0.21	1.06
Utilities	34	0.12	0.12	0.12	0.12
Sector total	4,554				
Total employment	5,689				

*Railcar and tank truck workers are unique to the BD monomer sector.

Source: Job categories and number of workers obtained from PEI.

Arithmetic means under current conditions obtained from PEI.

Arithmetic means under revised PEL's calculated from geometric statistics provided by PEI. [Ex. 30]

D. Benefits Analysis

The primary benefit of revising the OSHA standard for occupational exposure to BD will be the reduction in the incidence of BD related deaths and illnesses. Based upon current industry exposure levels and OSHA's preferred quantitative risk assessment (QRA) for cancer, OSHA estimates that approximately 25 cancer deaths related to occupational exposure to BD will occur over the next 45 years. Lowering

the PEL from the current level of 1,000 ppm to 10 ppm will prevent 14 (i.e., 56 percent) of the expected cancer deaths, lowering the PEL to 5 ppm will prevent 16.5 (i.e., 65 percent) of the expected cancer deaths, and lowering the PEL to 2 ppm will prevent 22 (i.e., 87 percent) of the expected cancer deaths. Table 32 provides a breakdown of the expected cancer deaths avoided under each of the regulatory alternatives. In addition to the estimated cancer reductions, OSHA anticipates that lowering the PELs for BD will reduce other adverse health effects (eg., teratogenic and reproductive effects), which can not be quantified at this time.

TABLE 32.—ESTIMATED NUMBER OF CANCER DEATHS PREVENTED OVER 45 YEARS UNDER VARIOUS 1,3-BUTADIENE PELS

[By industry sector, by job classification]

Job category	Estimated cancer deaths under current conditions	Estimated deaths prevented under following PELs—		
		10 ppm	5 ppm	2 ppm
Crude 1,3-Butadiene				
Process technicians:				
Tank farm	0.03	0.00	0.02	0.02
Pump alley	1.33	0.00	1.11	1.11
Control room	0.10	0.00	0.00	0.06
Laboratory technicians:				
Analysis	0.16	0.10	0.10	0.13
Cylinder voiding	2.89	2.54	2.82	2.82
Other: Maintenance	0.41	0.00	0.00	0.35
Sector total	4.92	2.64	4.05	4.49
1.3-Butadiene Monomer				
Process technicians:				
Railcar	0.82	0.67	0.67	0.79
Tank truck	0.05	0.00	04	0.04
Tank farm	0.04	0.00	0.03	0.03
Pump alley	0.95	0.00	0.79	0.79
Control room	0.05	0.00	0.00	0.03
Laboratory technicians:				
Analysis	0.10	0.06	0.06	0.09
Cylinder voiding	1.79	1.58	1.75	1.75
Other: Maintenance	0.62	0.00	0.00	0.52
Sector total	4.42	2.31	3.34	4.04
Polymer and Miscellaneous Chemical Production				
Process technicians:				
Unloading	0.36	0.29	0.29	0.35
Tank farm	1.21	0.94	0.94	1.15
Purification	7.18	5.63	5.63	6.40
Polymerization or reaction	0.61	0.00	0.00	0.00
Solution or coagulation	0.04	0.00	0.00	0.00
Crumbling and drying	0.01	0.00	0.00	0.00
Control room	0.02	0.00	0.00	0.00
Packaging	0.04	0.00	0.00	0.00
Warehousing	0.01	0.00	0.00	0.00
Laboratory technicians: Analysis	2.54	2.19	2.19	2.48
Other: Maintenance	3.76	0.00	0.00	3.01
Utilities	0.01	0.00	0.00	0.00
Sector total	15.79	9.05	9.05	13.39
Total	25.13	14.00	16.44	21.92

Source: U.S. Department of Labor, OSHA, ORA.

E. Cost of Compliance

OSHA estimates that compliance with the 10 ppm PEL/50 ppm STEL will result in annualized costs of approximately $0.9 million, compliance with the 5 ppm PEL/25 ppm STEL will result in annualized costs of approximately $1.5 million, and, compliance with the 2 ppm PEL/10 ppm STEL will result in annualized costs of approximately $3.2 million. Table 33 provides a breakdown of the compliance costs by provision for each of the regulatory alternatives.

TABLE 33.—SUMMARY OF COMPLIANCE COSTS BY REGULATORY ALTERNATIVE, PROVISION AND INDUSTRY

[Thousands of 1987 dollars]

Provision	Industry sector			
	Crude	Monomer	Polymer	Total
	10 ppm PEL, 50 ppm STEL and 5 ppm Action Level			
Engineering controls	99.2	73.7	183.8	356.7
Exposure monitoring	55.9	30.5	82.6	169.0
Medical surveillance	4.9	4.2	10.8	19.9
Respirators and tests	0.0	0.0	323.1	323.1
Information and training	1.5	0.8	4.9	7.2
Recordkeeping	6.7	2.9	13.7	23.2
Total industry costs	168.2	112.1	618.9	899.2
	5 ppm PEL, 25 ppm STEL and 2.5 ppm Action Level			
Engineering controls	138.9	85.8	260.5	485.2
Exposure monitoring	72.2	37.0	84.9	194.1
Medical surveillance	9.9	8.2	23.0	41.1
Respirators and tests	235.4	210.2	323.1	768.7
Information and training	1.9	1.2	8.4	11.5
Recordkeeping	7.0	3.1	15.5	25.6
Total industry costs	465.3	345.5	715.4	1,526.2
	2 ppm PEL, 10 ppm STEL and 1 ppm Action Level			
Engineering controls	138.9	85.8	260.5	485.2
Exposure monitoring	92.2	48.8	104.4	245.4
Medical surveillance	19.7	19.1	37.2	76.0
Respirators and tests	362.0	411.3	1,551.3	2,324.6
Information and training	2.9	2.3	12.4	17.6
Recordkeeping	7.5	3.6	17.5	28.6
Total industry costs	623.2	570.9	1,983.3	3,177.4

Source: Based on JACA (Ex. 30).

Under all three alternatives, respirators and engineering controls account for the preponderance of the costs. Respirators account for approximately 39 percent of the compliance costs under the 10 ppm PEL/50 ppm STEL alternative, 52 percent of the compliance costs under the 5 ppm PEL/25 ppm STEL alternative, and 73 percent of the compliance costs under the 2 ppm PEL/10 ppm STEL alternative. Engineering controls account for approximately 40 percent of the compliance costs under the 10 ppm PEL/50 ppm STEL alternative, 32 percent of the compliance costs under the 2 ppm PEL/10 ppm STEL alternative, and, 15 percent of the compliance costs under the 2 ppm PEL/10 ppm STEL alternative.

A comparison of these estimates with other comments submitted to the record reveals general agreement on the unit costs, but disagreement on the total costs. The report by Heiden and Associates (Ex. 28–14), which is based on an extensive survey of the 12 monomer facilities, illustrates this point.

There were three common controls described in Exhibit III–2 of the Heiden report and in the JACA recommendations: closed-loop sampling devices, magnetic tanks car gauges and leak detection devices. JACA estimated the capital cost of the closed-loop sampling devices to be $1,409 as compared to the Heiden estimate of $2,000. JACA estimated the capital cost of the magnetic gauges to be $2,800 as compared to the Heiden estimate of $1,450. And, JACA estimated the capital cost of the leak detection devices to be $7,000 which is identical to the Heiden estimate for valve/source monitoring. In addition, Heiden's estimate that 40 to 50 percent (5 or 6 plants out of 12) of the monomer facilities would require additional controls compares quite favorably with JACA's estimate that 50 to 75 percent of the additional controls would be required by the typical or model plant. Finally, both Heiden and JACA agree that additional respirator use will not be required under a 10 ppm PEL and that a 1 ppm PEL is infeasible without routine and extensive respirator use.

A comparison of the Heiden and JACA industry-wide compliance costs, however, does not indicate general agreement. Although, both Heiden and JACA developed compliance estimates for three PELs, the only PEL that they both studied was 10 ppm. This is because Heiden did not examine PELs between 10 ppm and 1 ppm, and, JACA did not develop cost estimates for PELs below the lowest feasible level (i.e., 2 ppm). In fact, OSHA finds it difficult to assess the meaning of Heiden's compliance cost estimates for the 1 ppm and 0.1 ppm PELs when Heiden says that achieving these levels is not feasible.

Heiden estimated that the BD monomer industry (including loading terminal operations) would incur approximately $967,400 in annualized engineering control costs to meet the 10 ppm PEL as compared to the JACA estimate of $107,900. Thus Heiden estimates that the engineering costs will be about nine times greater than the JACA estimate.

An analysis of these estimates reveals that the major difference between the two is that the Heiden estimate is based on the use of a far greater variety of engineering controls than was recommended by PEI. PEI's rationale for not recommending many of the controls in the Heiden survey is as follows:

> Several additional types of controls (such as purge facilities for sphere and tank gauges or closed tank gauging and drain facilities, valve elimination and upgrade, improved fugitive emission programs, and use of rupture disks) were also reported in a recent survey of monomer production plants by Heiden Associates * * * Such controls were not included in this report because they were

generally considered to be effective in controlling environmental releases, and not believed to have any significant impact on reducing occupational exposures. (Ex. 30)

In other words, since the OSHA regulatory alternatives do not place limits on environmental releases, JACA did not include controls that would reduce emissions in areas where workers are not present. In addition, unlike JACA, Heiden made no effort to develop a control strategy which utilized the low cost or "best available technology" (BAT). For example (as explained earlier), JACA did not suggest replacing or retrofitting existing pumps with dual mechanical seals (an expensive control recommended by Heiden), because under a 10 ppm PEL, JACA determined that the emissions from the pumps did not represent a significant occupational exposure problem, and, under the two lower PELs, JACA determined that the emissions could effectively be controlled with a leak detection program.

F. Economic Impacts and Regulatory Flexibility

OSHA examined the potential economic impacts of the regulatory alternatives on typical firms in each industry sector, based upon an analysis of compliance cost to revenue and profit ratios. If none of the compliance costs could be passed forward to customers, then the profit declines in the product lines impacted by the alternative BD standards would not exceed five percent for a typical firm in each of the industry sectors. If all of the compliance costs were to be passed forward to customers in order to leave profits unchanged, then the required revenue increases from the product lines impacted by the alternative BD standards would not exceed one tenth of one percent for an average firm in each industry sector. Since the analysis indicates that the size of the compliance costs are small in relation to both profits and revenues under these extreme or "bounding" cases (i.e., it is likely that some of the costs would be passed forward to customers and some absorbed), OSHA has preliminarily determined that these costs are economically feasible for typical firms in each of the industry sectors.

Finally, in accordance with the Regulatory Flexibility Act, OSHA examined the impact of the regulatory alternatives on small firms and has preliminarily determined that there will not be any adverse economic impacts on small firms in the industries under any of the three technologically feasible regulatory alternatives. CMA (Ex. 28–14) and JACA (Ex. 30) have provided lists of the firms engaged in the manufacture of crude BD and BD monomer. Correlating this list with public financial data reveals that most firms in these sectors are of substantial size in terms of both gross revenue and number of employees. In addition, since JACA reports that many of the facilities in these sectors are extremely similar in terms of age, size and capacity (Ex. 30), it is extremely unlikely that there will be any adverse differential impacts of small entities in the crude BD and BD monomer sectors.

JACA (Ex. 30) has also provided lists of the firms engaged in the manufacture of various BD polymers. Once again, correlating this list with public financial data reveals that most firms are of substantial size in terms of both gross revenue and number of employees. While there is substantial variation in the size of individual facilities in the BD polymer sector, a further examination of the lists of BD2 polymer producers reveals that the plants with the smallest reported capacities (i.e., less than a million pounds annually) are facilities of large corporations (eg., Goodyear Tire and Rubber, and, Occidental Petroleum).

Thus OSHA preliminarily concludes that the three regulatory alternatives will not have an adverse differential impact on small entities in any of the three potentially impacted sectors.

IX. Conclusion and Permissible Exposure Limit

OSHA considered the regulatory alternatives for 8-hour TWAs of 10 ppm, 5 ppm, 2 ppm, and 1 ppm, with corresponding STELs of 50 ppm, 25 ppm, 10 ppm, and 5 ppm. As discussed above in the significance of risk section, OSHA's preliminary risk assessment shows an excess cancer risk of 147 deaths per 1,000 workers over a 45-year working lifetime at the current PEL of 1,000 ppm. This risk is clearly significant. The proposal to reduce exposures to 2 ppm will achieve approximately a 97% reduction in risk or 142 lives saved per 1,000 workers who would have been exposed to a working lifetime exposure at current PEL of 1,000 ppm. This reduction in risk achieved by lowering the PEL to 2 ppm is clearly substantial.

In 1986, the Court of Appeals for the District of Columbia, in reviewing the ethylene oxide standard, held that: "If in fact a STEL would further reduce a significant health risk and is feasible to implement, then the OSH Act *compels* the agency to adopt it (barring alternative avenues to the same result)." *Public Citizen Health Research Group* U. *Tyson*, 796 F.2d 1479 (D.C. Cir. 1986). OSHA has found that significant risk of BD-related cancer exists at cumulative exposures below the proposed PEL. Compliance with a STEL would further reduce such risks by reducing the chance that air in the workplace will contain high levels of BD as a result of high short term BD exposures. The level of the STEL in this proposal, five times the PEL, is consistent with standards for other substance such as benzene which was recently promulgated by OSHA.

As discussed above in the technological and economic feasibility sections, OSHA's analysis shows that a regulatory alternative of 1 ppm PEL/5 ppm STEL is not technologically feasible without the extensive use of respiratory protection. It also shows that under a 10 ppm PEL/50 ppm STEL, engineering and work practices controls would be adequate 99.5 percent of the time during which respiratory protection would not be required, while under 5 ppm PEL/25 ppm STEL and 2 ppm PEL/10 ppm STEL, the percentages of time compliance could be met by engineering and work practice controls alone are 98.3% and 92.1%, respectively. OSHA estimates that compliance with the 10 ppm PEL/50 ppm STEL will result in annualized costs of approximately $0.9 million, while for compliance with 5 ppm PEL/25 ppm STEL and 2 ppm PEL/10 ppm STEL, the annualized costs would be approximately $1.5 million and $3.2 million, respectively. Since the analysis indicates that the size of the compliance costs is small in relation to both profits and revenues, OSHA has preliminarily determined that these costs are economically feasible for typical firms in each of the industry sectors. A proposed standard higher than 2 ppm PEL/10 ppm STEL may be less expensive but would also be less protective and the predicated risks of excess cancer death would be substantially greater. Conversely, a proposed standard lower than 2 ppm PEL/10 ppm STEL would be more expensive and may be technologically and economically infeasible for many operations, with too many workers wearing respirators most of the time. Extensive respiratory use is not an effective control technique. OSHA believes that a proposed standard of 2 ppm PEL/10 ppm STEL is technically and economically feasible based on data indicating that several industries or industry segments are presently controlling exposures to or very near this level.

An action level of 1 ppm is included in the proposal of 2 ppm PEL/10 ppm STEL. OSHA believes many employers will choose to achieve the action level 1 ppm with engineering and work practice

controls, in order to save on the cost of monitoring, industrial hygiene and medical provisions which are required for employees exposed over the 1 ppm action level. For workplaces with BD exposures below the action level of 1 ppm, such requirements will not be triggered. Thus employers will have a strong incentive to reduce exposures below the action level.

OSHA believes that industrial hygiene measures such as engineering and work practice controls and personal protective equipment as well as monitoring, training, and medical surveillance provisions will provide substantial but not complete additional protection for employees exposed between 2 ppm and 1 ppm. Respirators are permitted to be used in certain situations where engineering controls are deemed to be infeasible (i.e., maintenance) will provide further protection. Compliance with these provisions will result in less exposure to employees.

In light of the above, OSHA is proposing a standard of 2 ppm PEL/10 ppm STEL with a 1 ppm action level to substantially reduce a significant risk of cancer as low as is technologically and economically feasible. The Agency will, of course, consider all evidence presented in the rulemaking on issues presented including alternative exposure limits.

XI. Summary and Explanation of the Proposed Standard:

OSHA believes that the proposed requirements set forth in this notice are those which, based on currently available data, are necessary and appropriate to provide adequate protection to employees exposed to BD. In the development of the proposal, OSHA has considered all recommendations received in response to the ANPR as well as numerous reference works, journal articles, and other data accumulated by OSHA since initiation of this rulemaking.

A. Scope and Application: Paragraph (a)

This proposed standard would apply to all workplaces in all industries, including construction and maritime as well as general industry, where BD is produced, released, stored, handled, used, or transported, and over which OSHA has jurisdiction. An exemption provision, however, has been provided in the proposal.

This section does not apply to the processing, use, and handling of products containing BD where objective data demonstrate that the product cannot release BD above the action level under the expected conditions of processing, use, and handling which will cause the greatest possible release. It is likely that in a number of products made from, containing or treated with BD, there may be insignificant residual BD present to the extent that minimal exposure would be expected. This determination (that air concentrations will not exceed the action level) need not be based on data generated by the processor but may, for example, be based upon information provided by the manufacturer. The provision enables fabricators or users of products made from, containing or treated with BD to avoid the burdens of compliance with the standard where exposures are minimal.

It should be noted that where objective data are not available to satisfy the condition for exemption, the employer is required to perform, at the very least, initial monitoring of employee exposures to BD. If the results of initial monitoring indicate employee exposures are below the action level, the employer may discontinue monitoring for those employees and is relieved of other obligations under the proposal, except for the labeling requirements in paragraph (j). Thus, even if operations are not specifically exempted from the proposal, keeping exposure levels below the l ppm "action level" will relieve many employers from further duties under the standard. This provision has been incorporated in a number of OSHA standards (acrylonitrile 29 CFR 1910.1045; 43 FR 45809 (1978); arsenic 29 CFR 1910.1018; 43 FR 19624 (1978), ethylene oxide 29 CFR 19l0.1047; 49 FR 5796 (1984); 53 FR 11413 (1988)).

It should be noted that while the Hazard Communication standard generally exempts materials containing less than 0.1 percent of a potential carcinogen (as defined in that standard), any material containing BD that is capable of causing exposure is covered even if the 0.1 percent exemption applies. The Hazard Communication Standard would apply if the exposures present a health hazard even if the exposure is less than the PEL. While these uses of BD would not be covered under the BD proposal, they would still require labeling and other provisions under the Hazard Communication standard. (29 CFR 1910.1200(d)(5)(iv)).

B. Definitions: Paragraph (b)

An "action level" of 1 ppm (8-hour time-weighted average), is provided in the proposal. The purpose of the action level is to relieve the burden on employers by providing a cut-off point for required compliance activities under the standard. In addition, due to the variable nature of employee exposures to airborne concentration of BD, the concept of an action level provide a means by which the employee may have greater assurance that the employees will not be exposed to BD over the PEL.

The action level also increases the cost-effectiveness and performance orientation of the standard while improving employee protection. Employers who can, in a cost-effective manner, come up with innovative methodology to reduce exposures below the action level, will be encouraged to do so in order to save on the expenses for the monitoring and medical surveillance provisions of the standard. Their employees will be further protected because their exposures will be less than half of the permissible exposure limit. When employers do not lower exposures below the action level, employees above the action level will have protection of medical surveillance, monitoring and other provisions of the standard to give further protection from the effects of BD.

The statistical basis for using an "action level" has been discussed in connection with several other OSHA health standards (see, for example, acrylonitrile (29 CFR 1910.1045; 43 FR 45809 (I978)). In brief, although all measurements on a given day may fall below the permissible exposure limit, some possibility exists that on unmeasured days the employee's actual exposure may exceed the permissible limit. Where exposure measurements are above the action level, the employer cannot reasonably be confident that the employee may not be overexposed. Therefore, requiring periodic employee exposure measurements to begin at the action level provides the employer with a reasonable degree of confidence in the results of his measurement program (Ex. 23–67). OSHA's specific choice of setting an action level of one-half the PEL is based on its successful experience in utilizing one-half the PEL as the action level in many standards, such as arsenic, ethylene oxide, vinyl chloride and benzene.

The action level provides a way of maximizing employee protection in those instances where exposures are possibly significant, and minimizing employer obligations by defining the point below which no action is necessary. Use of the action level concept will result in the necessary inclusion of employees under the proposed standard, whose exposures are above the action level and for whom further protection is warranted. The action level mechanism will also greatly limit the number of workplaces covered

under the standard because employers whose employees are under the action level will be exempt from most provisions of the standard. The action level concept therefore provides an objective means of tailoring different sections of the standard to those employees who are at the greatest risk of developing adverse health effects from exposure to BD.

The chemical "1,3-butadiene" (Chemical Abstracts Registry Number 106-99-0) is a colorless, noncorrosive, flammable gas with a mild aromatic odor at standard ambient temperature and pressure. It has a chemical formula of C_4H_6, a molecular weight of 54.1, and a boiling point of −4.7°C at 760 mm Hg, a lower explosive limit of 2%, and an upper explosive limit of 11.5%. Its vapor density is almost twice that of air. It is slightly soluble in water, somewhat soluble in methanol and ethanol, and readily soluble in less polar organic solvents such as hexane, benzene, and tolunene. It is highly reactive, dimerizes to 4-vinylcyclohexene, and polymerizes easily. Because of its low odor threshold, high flammability and explosiveness, BD has been handled with extreme care in the industry.

"Day" is defined as any part of a calendar day. Therefore, if a requirement is applicable for an employee who is exposed to BD for 10 days in a calendar year, that requirement becomes applicable to an employee who is exposed to BD for any part of each of 10 calendar days in a year.

"Director" means the Director of the National Institute for Occupational Safety and Health, U.S. Department of Health and Human Services or designee.

A definition of the term "emergency" is included in the proposed standard. For the purposes of the standard, emergencies are occurrences such as, but not limited to, equipment failure, rupture of container, or failure of control equipment which may or do, result in unexpected significant releases of BD. Sections of the proposed standard that include provisions that must be met in case of emergencies include Respiratory Protection, Medical Surveillance, and Employee Information and Training. Every spill or leak does not automatically constitute an emergency situation. The exposure to employees must be high and unexpected. This is a performance oriented provision relying on judgment. It is not possible to specify detailed circumstances which constitute an emergency.

"Employee exposure" is defined as that exposure to airborne BD which would occur if the employee were not using respiratory protective equipment. This definition is consistent with OSHA's previous use of the term "employee exposure" in other health standards.

"Regulated area" means areas where airborne concentrations of BD are in excess of the permissible exposure limit. This is explained in the Regulated Area discussion below.

C. Permissible Exposure Limit: Paragraph (c)

OSHA proposes to revise the PEL for BD by deleting the current 1,000 ppm standard contained in 29 CFR 1910.1000, Table Z-1 and setting an 8-hour time weighted average exposure limit of 2 ppm. This proposed PEL is based on underlying findings by OSHA that occupational exposure to BD under current permissible exposure levels presents a significant risk to employees and that the new standard will achieve a substantial reduction in that risk.

The basis for the 8-hour permissible exposure limit is discussed above in the sections on significant risk, feasibility and choice of exposure limit. OSHA believes lowering the current PEL to 2 ppm TWA substantially reduces a significant risk and is feasible for industry to achieve.

Short Term Exposure Limit (STEL): OSHA proposes a Short Term Exposure Limit (STEL) of 10 ppm BD for 15 minutes. This proposal is based on animal data which indicate that short-term exposure to BD induces a stronger carcinogenic response than does long-term exposure at a lower equivalent dose (Ex. 29-4). There are epidemiological data which suggest this same relationship (Exs. 2-27 and 23-22).

The National Toxicology Program has conducted a second two-year inhalation bioassay to measure the carcinogenic potency of BD in B6C3F, mice. At present, only data from early death animals (through week 65) and interim sacrifices have been presented (Ex. 29-4). As part of that bioassay, groups of mice were used for a stop-exposure study. That is, groups of mice were exposed to equivalent cumulative doses of BD but under different exposure scenarios. One group of male mice was exposed to 312 ppm BD for 52 weeks (16,224 ppm-weeks), while a second group was exposed to 625 ppm BD for 26 weeks (16,250 ppm-weeks). The incidence of lymphoma was markedly reduced in the former group as compared to the latter. This indicates that equivalent cumulative doses of BD do not induce equivalent carcinogenic responses. OSHA is proposing a STEL for BD because the incidence of cancer from BD exposure does not depend on cumulative dose alone.

The epidemiological evidence suggests this same conclusion. As discussed in the carcinogenic health effects of this preamble, in a study of 13,920 styrene-butadiene rubber workers, the highest standardized mortality ratio (SMR) for all lymphohematopoietic cancers was observed in utility workers (Obs=5; Exp=2.46; SMR=2.03) (Ex. 23-22).

These are workers who are not routinely exposed to BD, but when they are exposed, their exposures are usually high (Ex 2-27). In comparison, production workers with routine exposures at lower levels had a lower SMR for death from lymphohematopoietic cancers (Obs=19; Exp=13.05; SMR =146). This evidence lends further support to the need for a STEL for BD exposure.

The proposed standard allows a STEL of 10 ppm as long as the 8-hour TWA is no greater than 2 ppm. If the health effects of BD are related to total dose alone, without regard to temporal distribution of that dose, an 8-hour TWA limit on exposures will reduce the risk of those health effects by limiting the total dose received. However, if the effects from exposure can be shown to be greater when the total dose is received in a short period than when it is spread over a longer period, an 8-hour TWA limit alone might not be adequate to reduce the risks. In the event of such a "dose-rate" relationship being established, a STEL might be warranted as a supplement to the TWA in order to provide protection against additional risk attributable to concentration of the dose over short periods.

D. Exposure Monitoring: Paragraph (d)

The proposed standard imposes monitoring requirements pursuant to section 6(b)(7) of the OSHA Act (29 U.S.C. 655) which mandates that any standard promulgated under section 6(b) shall, where appropriate, "provide for monitoring or measuring of employee exposure at such locations and intervals, and in such manner as may be necessary for the protection of employees." The purposes of requiring air sampling for employee exposure to BD include the prevention of overexposure of employees; the determination of the extent of exposure at the worksite; the identification of the source of exposure to BD; and collection of exposure data by which the employer can select the proper control methods to be used and to evaluate the effectiveness of the selected methods. Monitoring enables employers to meet the legal obligation of the standard to assure that their employees are not

exposed to BD in excess of the prescribed levels, and to be able to notify employees of their exposure levels, as required by section 8(c)(3) of the Act. In addition, collection of exposure monitoring data enables the examining physician to be informed of employee exposure levels.

Exposure monitoring is also important to determine the exact level of BD to which employees are exposed. This determines what other requirements of the standard will have to be met. Major sections of the standard are triggered if an employee is exposed above the action level and are not required if the employee is not exposed.

The exposure monitoring provisions require the employer to determine the exposure for each employee exposed to BD. This does not mean that separate measurements for each employee must be taken but rather "representative employee exposure" is to be determined. Samples must be taken within the employee's breathing zone (also known as "personal breathing zone samples" or just "personal samples"). The samples used to determine whether the employee is exposed above the action level must represent the employee's exposure to airborne concentrations of BD over an eight-hour period without regard to the use of respirators. Representative 15-minute short-term employee exposures are to be determined on the basis of one or more samples representing 15-minute exposures associated with operations that are most likely to produce exposures above the short term exposure limit for each shift for each job classification in each work area. Here, too, respirators cannot be a factor. (See "Employee exposure", as defined in the definitions section). Full-shift sampling must be conducted for each job classification in each work area. These samples must consist of at least one sample representative of the entire shift or consecutive samples taken over the length of the shift.

Representative exposure sampling is permitted when there are a number of employees performing essentially the same job under the same conditions. For these types of situations, it may be sufficient to monitor a fraction of such employees in order to obtain data that are "representative" of the remaining employees. As permitted in paragraph (d), representative personal sampling for employees engaged in similar work and exposed to similar BD levels can be achieved by measuring that member of the exposed group reasonably expected to have the highest exposure. This result would then be attributed to the remaining employees of the group.

To eliminate unnecessary monitoring and improve the cost-effectiveness of the standard, paragraph (d)(1)(iv) allows employers who can document that exposure levels are the same for similar operations in different work shifts throughout the work day, to sample only the shift for which the highest exposures are expected to occur. This provision does not apply to initial monitoring requirements. The employer must be able to demonstrate that employees on the shifts who are not monitored, are not likely to have exposures higher than those of the shifts monitored.

Workplace exposure monitoring is initially required of all employers who have a place of employment covered under the scope of this standard. In addition, the proposed standard requires that the initial monitoring be conducted within 60 days of the effective date of the final standard or the introduction of BD to the work place. OSHA believes that initial monitoring can be completed within that time. To eliminate unneeded requirements, if an employer has workplace monitoring data from within one year prior to the effective date, those data will be allowed to satisfy the requirements of the initial monitoring.

This provision is designed to make clear that OSHA does not intend to require employers who have voluntarily performed employee monitoring to repeat such monitoring if they have reliable and objective data showing that their employees are not exposed to BD above the permissible exposure limits.

The results of the initial monitoring represent the data which will be used to determine when further periodic monitoring will be required. If exposures are below the action level, then no further monitoring would be required unless processes or products change which are likely to lead to higher exposure. If the initial monitoring results show employee exposures at or above the action level, but at or below the 8-hour TWA limit, then the employer must repeat monitoring for these individuals every six months. If exposures are above the 8-hour TWA limit, then the employer must remonitor every three months. If the employee's exposure is above the STEL, the employee shall repeat such monitoring at least every three months until the employee's exposure falls to or below the STEL. If, in subsequent monitoring, results indicate that an employee's exposure, as determined by two consecutive measurements taken at least seven days apart, falls from above the 8-hour TWA to between the 8-hour TWA and the action level, then monitoring need only be done every six months, unless production changes may lead to higher exposures. Similarily, when the two consecutive measurements indicate the exposure has dropped below the action level, further monitoring can be discontinued. OSHA believes those frequencies, which are similar to other OSHA standards such as Ethylene Oxide are sufficient.

OSHA's proposed monitoring of employees whose exposures are between the action level and the 8-hour TWA every six months is based on several factors. While these employees have been shown to be exposed to levels of BD below the 8-hour TWA, their levels of exposures are not so far below the PELs that monitoring could safely be discontinued. Even minor changes in engineering controls or work practices could result in exposures increasing to levels above the PEL. Remonitoring on a semi-annual basis will enable the employer to be confident his or her controls are working or, in the event exposures are shown to exceed the 8-hour TWA, alert the employer as to the need for additional controls.

In short, the standard would contain a TWA, a STEL and an action level. The interrelationship among these three exposure levels would determine the frequency at which employers are obligated to monitor employee exposures. There would be six possible exposure scenarios, or combinations of TWA and short-term exposures, that would determine the frequency of required monitoring. Table 34 lists these six exposure scenarios, along with their monitoring frequencies.

TABLE 34.—EXPOSURE SCENARIOS AND MONITORING FREQUENCIES

Exposure scenario	Required monitoring activity
Below the action level and at or below the STEL.	No 8-hour TWA monitoring required.
Below the action level and above the STEL.	No 8-hour TWA monitoring required; monitor STEL exposures every three months.
At or above the action level, at or below the TWA, and at or below the STEL.	Monitor 8-hour TWA exposures every six months.
At or above the action level, at or below the TWA, and above the STEL.	Monitor 8-hour TWA exposure every six months and monitor STEL exposures every three months.
Above the TWA and at or below the STEL.	Monitoring 8-hour TWA exposures every three months.
Above the TWA and above the STEL.	Monitor 8-hour TWA exposures and STEL exposures every three months.

As shown by the table above, the action level trigger largely determines whether employers must monitor employees exposure to BD. The only exception would be the scenario in which 8-hour TWA exposures are below the action level and short-term exposures are above the STEL. In this particular case, the existence of an STEL would obligate employers to monitor short-term exposures four times per year at those job locations where the STEL is exceeded, but employers would not be obligated to monitor 8-hour TWA exposures at those job locations.

Employers are allowed to terminate monitoring of employees for whom initial monitoring results indicate their exposure to be below the action level. Furthermore, if periodic monitoring results indicate, by at least two consecutive measurements taken at least seven days apart, that employee exposures are below the action level, the employer may discontinue monitoring for these employees. OSHA recognizes that monitoring may be a time-consuming, expensive endeavor and therefore offers employers the incentive to be allowed to discontinue monitoring for employees whose sampling results indicate exposures below the action level. It is hoped that such a provision to allow the employer to stop monitoring employees whose exposure to BD falls below the action level will encourage employers to keep exposures to BD below the action level in their workplaces, thereby keeping exposures to a minimum and saving themselves the time and expense of monitoring and other applicable provisions of the proposal as well.

Employees will continue to be protected even when periodic monitoring has ceased because of the requirements of paragraph (d)(5). Additional monitoring is required by paragraph (d)(5)(i) when there has been a process or production change or a change in control equipment, personnel or work practices which may result in new or additional exposures to BD. There may also be times within the employer's own workplace when the employer may suspect a change which may result in new or additional BD exposure; the employer is obligated by this paragraph to monitor at these times also. Instead of trying to define each and every situation where the employer must monitor for new or additional exposures to BD, it is intended by this section that the employers will institute this additional monitoring when the employer has any reason to suspect a change.

Paragraph (d)(5)(ii) specifically requires additional monitoring to be conducted whenever spills, leaks, ruptures or other breakdowns occur. Such occurrence can result in very high exposures. After the clean-up of the spill or repair of the leak employers must perform redeterminations of airborne exposure levels for those employees who may be exposed at such areas of their worksites. Such redetermination provides one method of ascertaining that proper corrective methods have been instituted and employee exposures are not significantly altered from what they were prior to the leak or spill.

The employer is required to use monitoring and analytical methods which have an accuracy (at a confidence level of 95 percent) of not less than plus or minus 25 percent for airborne concentrations of BD and within plus or minus 35 percent for airborne concentrations of BD at or above the action level and to below the TWA limit of 2 ppm. Methods of measurement are presently available to detect BD to this accuracy level at levels of 0.155 ppm. One such method is described in Appendix D. Sampling and analysis may also be performed by portable direct reading instruments, real-time continuous monitoring systems, passive dosimeters or other suitable methods. The employers have the obligation to select a monitoring method which meets the accuracy and precision requirements of the standard under the unique conditions which exist at the employee's worksite.

The proposed standard further requires that employers notify each of their employees in writing, either individually or by posting in an appropriate location accessible to affected employees, the results of personal monitoring samples. The employer is obligated to do this within 15 working days after the receipt of the results. In addition, the written notification must contain the corrective action(s) being taken by the employer that will reduce the employee's workplace exposure to or below the 8 hour TWA and 15-minute STEL, where ever the 8-hour TWA or the 15-minute STEL is exceeded. This requirement, in keeping with other recent OSHA health standards, allows the employer to post written exposure monitoring results in an easily accessible location, or allows the employer to notify individuals in writing of their monitoring results, whichever better suits that employer's worksite. The requirement to inform employees of the corrective actions the employer is going to take to reduce the exposure level to below the PELs is necessary to assure employees that the employer is making efforts to furnish them with a safe and healthful work environment, as required by section 8(c)(3) of the Act.

The employer is also required to allow employees or their designated representatives an opportunity to observe the employee exposure monitoring. This provision is also required by statute (Section 8(c)(3) of the OSH Act) and is provided for in paragraph (m) of the proposal, as is discussed in more detail below.

OSHA solicits comment on the proposed frequency of monitoring and any other aspects of exposure monitoring.

E. Regulated Areas: Paragraph (e)

The proposal would require employers to establish a regulated area where airborne exposures to BD exceed the PELs. Access to the regulated area would be restricted to authorized persons and the areas themselves are to be demarcated in any manner that limits the number of persons exposed to BD within these areas. This provision applies when the PELs are likely to be exceeded, but it does not apply to inadvertent releases covered under paragraph (h) on emergency situations.

The purpose of a regulated area is to ensure that employers make employees aware of the presence of BD at levels above the PELs in the workplace and to limit BD exposure to as few employees as possible. The establishment of a regulated area is an effective means of limiting the risk of exposure to substances known to be or suspected of having potential carcinogenic activity in humans. Because of the serious nature of the possible exposure and the need of persons entering the area to be protected by properly fitted respirators, the number of persons given access to the area is to be limited to only those employees needed to do the job.

The final standard gives employers a choice of whether to use, for example, ropes, markings, temporary barricades, gates, or more permanent enclosures to demarcate and limit access to these areas. Factors that employers might consider in determining the type of identification system include the configuration of the area, whether the regulated area is permanent, the airborne BD concentration, the number of employees in adjacent areas, and the period of time the area is expected to have exposure levels above the PEL. Permitting employers to choose how best to identify and limit access to regulated areas is consistent with OSHA's belief that employers are in the

best position to make such a determination based on the specific conditions of their workplaces.

Paragraph (e)(4) also requires that, whenever an employer at a multi-employer worksite establishes a regulated area, that employer must communicate effectively the location and access restrictions to other employers at the worksite. Such communication would lessen the possibility that unauthorized persons would enter the area or that workers not involved in BD-related operations would be exposed inadvertently. OSHA would require employers whose employees are exposed to BD at concentrations above the PELs to be responsible for coordination of their work with other employers whose employees could suffer excessive exposure because of their proximity to the source of exposure to BD.

The regulated area provision reflects OSHA's concern that the employees at nearby sites be aware of the existence of the hazard and respect the need to remain outside of the perimeters delineated as a regulated area. While this could be accomplished by the employees of the second employer simply reading the signs posted by the first employer, this would not assign accountability. If the second employer is aware of the hazards, then it is the responsibility of the second employer to assure that his employees do not enter the regulated area of the first employer without permission and proper protective equipment.

F. Methods of Compliance: Paragraph (f)

The proposed standard would require the employer to reduce employee exposures to within the permissible limit by use of feasible engineering controls and work practices. Employers would be required to institute engineering controls and work practices to reduce exposures to the lowest feasible level even if these measures, alone, would not reduce the concentration of airborne BD below the PELs. The employer would be required to supplement these controls with respirators to ensure that employees are not exposed to BD at levels above the PELs.

OSHA would require that employers use engineering controls to comply with the proposed standard, because these controls would reduce exposure hazards in the working environment by removing, at least in part, the contaminant from the air. OSHA has found that employers also generally need to modify their work practices in order to operate engineering controls effectively. OSHA considers the use of respirators to be the least satisfactory approach to exposure control because they provide adequate protection only if employers ensure that respirators are properly fitted and worn. Unlike engineering controls and work practices, respirators are intended to protect only the employees who are wearing them from a hazard, rather than reducing the hazard. Accordingly, OSHA would permit reliance on respirators only insofar as employers can demonstrate that the engineering controls and work practices needed to comply with the PEL are infeasible.

There are certain activities where exposures are intermittent in nature and limited in duration, most often those involving maintenance and repair operations as well as those in emergency situations, where the use of engineering and work practice controls is not feasible. Where engineering controls are not feasible, the employer, nevertheless, has the obligation to protect employees. This obligation may require the use of respirators as a primary means of control.

OSHA policy on respirator use has been spelled out in the Respiratory Protection Standard, 29 CFR 1910.134(a)(1), which applies to all exposures to airborne toxins, and in the Air Contaminant Standard 29 CFR 1910.1000(e), which applies to exposures to all substances listed in Tables Z–1–A, Z–2, and Z–3. This policy was inherent in the national consensus standards which were adopted by OSHA in 1971, pursuant to section 6(a) of the OSH Act of 1970.

Subsequent additions to subpart Z, which were developed through section 6(b) rulemaking proceedings also reflect OSHA's determination that employers must control hazards by engineering controls and work practices instead of respirators to the extent feasible.

Based on the belief of OSHA and general industrial hygiene community that engineering controls should be the primary means of compliance, OSHA has concerns regarding JACA's recommendation that the emissions from pumps, and consequently workers' exposure to BD can be controlled more "cost-effectively" with the use of leak detection program rather than with double mechanical seals (Ex. 30). OSHA's concern with JACA's recommendation relies on the fact that a leak detection program is not a real-time measurement. Leak detection program is defined by JACA as a periodic inspection of pumps and compressors (potential sources of leaks) with an organic vapor analyzer (Ex. 30). For leak occurence between inspection times, employees may not become aware of their exposure to BD and consequently a false security situation may be created. Furthermore, the availability of an organic vapor analyzer to meet the detectability and specificity for BD at the PELs has not yet been established. Since double mechanical seals are currently available and employed as a conventional control technology by BD industry, OSHA is soliciting information and comments regarding the feasibility of this method of control in lieu of JACA's recommendation of leak detection program. OSHA's request for comments is based on the fact that among fourteen BD monomer producers (with over 90 percent of domestic BD production) responding to CMA's survey, six currently use double mechanical seals on pumps (Ex. 3–21). In this regard, Heiden Associates, Inc., an independent economic consulting firm located in Washington, D.C. recommends replacing or retrofitting existing pumps with double mechanical seals (Ex. 28–14). Heiden Associates, Inc. was commissioned by CMA to conduct a regulatory compliance study of the economic and technical implications of alternative specifications of the proposed regulation. This is an indication that the industry is willing to employ double mechanical seal pumps in the remaining eight BD monomer producers as means of controlling emissions from pumps and their subsequent worker exposures. OSHA believes that continuous monitoring with an alarm system to alert workers of leak occurence may be proven to be a feasible and effective alternative control technology. This control technology would definitely lessen the extent and the magnitude of workers exposure, if maintenance or repair work is performed promptly.

Paragraph (f)(2) requires employers who experience exposure in their work places over the PELs to establish and implement a written compliance program which describes the methodology to be used to reduce employee exposure to or below the PELs within their workplaces. No written compliance program is required if the exposure levels are already below the PELs. The written plan must provide feasible engineering and work practice controls and include a schedule for implementation, and must be furnished upon request for examination and copying to OSHA, NIOSH, and affected employees or their representatives. Once a workplace is in compliance with the standard, the written compliance plan need not be updated. If exposures later increase over the PELs; however, an update must be prepared. The written compliance plans is to be revised as

appropriate. Circumstances requiring revision of the compliance plan may include a change in controls or substantially different exposure conditions.

G. Respiratory Protection; Protective Clothing and Equipment: Paragraph (g)

When engineering controls and work practices cannot reduce employee exposure to BD to below the PELs, the employer must protect employees' health by the use of respirators. Specifically, respirators must be used while feasible engineering and work practices controls are being installed, in work operations such as maintenance and repair where engineering and work practice controls are infeasible and exposures are intermittant and limited in duration, where implementation of feasible engineering and work practice controls are exhausted but are not yet sufficient to reduce exposures below the PELs, and in emergencies. These limitations on the required use of respirators are consistent with the requirements of other OSHA health standards (e.g. asbestos, 1910.1001; ethylene oxide 1910.1047; benzene, 1910.1028), and with good industrial hygiene practice. They reflect OSHA's determination, as detailed in the preceeding section on methods of compliance, that respirators are inherently less reliable than engineering and work practice controls. OSHA has proposed, therefore, to allow reliance on respirators to control exposures above the PEL only in designated situations.

OSHA published an advance notice of proposed rulemaking on February 22, 1983, (48 FR 7473) to solicit public comments on the use of engineering controls and respirators to control employee exposure to air contaminants. As a rule, OSHA prefers the use of engineering controls where feasible to respiratory protection. However, many employers felt the need for increased flexibility in the use of respiratory protection. Based on data received in response to the ANPR, OSHA published a **Federal Register** notice on June 5, 1989, (54 FR 23991) proposing to incorporate additional flexibility in its methods of compliance requirements by more explicitly setting forth circumstances under which respiratory protection may be used due to the general infeasibility of implementing engineering controls. They are: (1) During the time necessary to install feasible engineering controls; (2) Where feasible engineering controls result in only a negligible reduction in exposures; (3) During emergency, life saving, recovery operations, repair, shutdowns and field situations where there is a lack of utilities for implementing engineering controls; (4) Operations requiring added protection where there is a failure of normal controls; and (5) Entries into unknown atmospheres.

In addition, OSHA requested public comment on other ways of allowing the employer to place greater reliance on the use of respirators to protect workers. Specifically, the Agency asked whether it is necessary to require all feasible engineering controls be installed for maintenance activities; whether respirator use should be permitted for any work situation in which the hazardous exposure is of very brief duration or at any time to achieve compliance with the STEL; and whether respirator use could be allowed in instances where the protection afforded by respirators was equal to, but less costly than, that provided by engineering controls. The proposal also requested information on whether equivalent protection for employees could be achieved by allowing respirator use in lieu of engineering controls for some substances while at the same time requiring employers who choose this option to do something extra, such as submit a written plan to the Agency that demonstrates how respirators provide protection equal to that provided by feasible engineering controls in the given work situation. Finally, OSHA asked for comment on the appropriateness of allowing employers to comply with exposure limits at all times by any method the employer deems advisable, an allowance which would, in effect, abolish OSHA's traditional hierarchy of controls.

This BD proposal requires employers to provide respirators to employees and to ensure that employees use the respirators properly. As in other OSHA standards, the employers are to provide the respirators at no cost to the employees. OSHA views this allocation of costs as necessary to effectuate the purposes of the Act. This requirement would make explicit an agency position which has long been implicit in the promulgation of health standards under section 6(b) of the Act.

The proposal also contains a table (Table 35) listing the types of respiratory protection to be provided based on airborne concentrations of BD in the workplace. The respirator selection table is consistent with OSHA's experience of the performance capabilities of the various types of respirators available.

Where employees are exposed to levels of BD greater than 50 ppm and respirator usage is permitted, positive pressure atmosphere supplying respirators must be used (See Table 35). These respirators supply uncontaminated air to the user rather than mechanically cleaning the BD contaminated atmosphere. Employers may always use a respirator with a higher level of protection in lower concentrations of BD. For example, a supplied air respirator may be used when exposures are 20 ppm.

Employers shall select respirators from those certified as being acceptable for protection against BD by the Mine Safety and Health Administration (MSHA) and by the National Institute for Occupational Safety and Health (NIOSH), under the provisions of 30 CFR part 11. NIOSH has proposed the revision of the 30 CFR part 11 respirator certification requirements (52 FR 32401) and their repromulgation as 42 CFR part 84. OSHA is reviewing the NIOSH proposed respirator certification changes, and will be following the progress of the NIOSH's rulemaking on certification program. However, whether under the current 30 CFR part 11 standards, or under the new 42 CFR part 84 standards when they are finalized, OSHA will be requiring the use of NIOSH certified respirators.

Whenever respirator use is permitted under the proposal to control exposures to BD, the employer must implement a comprehensive respiratory protection program. The protection program must include the elements set forth in the general respiratory protection standard, 29 CFR 1910.134 which contains basic requirements for proper selection, fit, use, training of employees, cleaning, and maintenance of respirators. For employers to ensure that employees use respirators properly, OSHA has found that the employees need to understand the respirator's limits and the hazard it is protecting against in order to appreciate why specific requirements must be followed when respirators are used.

OSHA is currently revising its general respiratory protection standard, and will be updating and expanding the current 29 CFR 1910.134 provisions to account for advances in respiratory protection, fit testing and selection, and other changes in respiratory protection practices since the current standard was adopted in 1971. Since the respiratory protection revision rulemaking and the BD standard revision are taking place concurrently, OSHA has utilized the respiratory experience gained during the revision of 29 CFR 1910.134 in preparing the respirator provisions of this BD proposal. OSHA requests comments on all of the respirator provisions in the

proposal and their effects on the use of respirators to control exposures to BD.

When air purifying respirators are used, the employer is required to replace the air purifying element at 90% of the expiration of service life or at the beginning of each shift in which they will be used. This is because the breakthrough times for cartridges with BD are short. NIOSH performed a respirator cartridge breakthrough study with BD (EX. 23–83) which showed breakthrough times from 55 to 92 minutes for cartridges exposed to BD concentrations of 75 ppm and 93 ppm. These short service life durations for cartridges are troubling. Since the useful service lives with cartridges for BD are too short to provide an adequate margin for safety, OSHA is proposing that only canisters, front or back mounted (industrial size), be allowed for use with BD when air purifying respirators are used. These large capacity filters (canisters) are needed to provided an adequate filtering capacity. In order to assure adequate canister capacity, OSHA requires that each organic vapor canister provide a minimum service life of four hours when it is tested under the maximum BD concentration expected in the workplace. Currently the proposed challenge testing protocol would require that canisters be tested at 25 °C, 85% relative humidity, 64 liters per minute air flow and at a concentration of 150 ppm of BD. The air flow will be 115 and 170 liters per minute, respectively, for tight and loose fitting powered air-purifying respirators. OSHA solicits comment on whether the current challenge protocol should be incorporated into the regulation.

The standard permits employees to leave the regulated area to readjust the respirator facepiece to their faces for proper fit. The respirator wearer who detects the odor of BD or who feels eye irritation should leave the area immediately and replace the air purifying elements before reentry. It also permits them to leave the regulated area to wash their faces to avoid potential skin irritation associated with respirator use.

Employers will be required to perform fit testing in accordance with 29 CFR 1910.134. In the proposed revision of 29 CFR 1910.134, initial and annual fit testing will be required for respirator wearers. Qualitative fit testing has been validated for protection factors of 10 times the 8-hour TWA, which for BD means a level of 20 ppm, with quantitative fit testing required for higher concentrations. Under the provisions of the respirator proposal, employers in BD workplaces would be allowed to use qualitative fit testing for respirators up to an exposure level of 20 ppm of BD. In order to use respirators in areas that require higher protection factors, quantitative fit testing would have to be used.

When tight fitting respirators are used, OSHA would require respirator fit testing because proper fit is critical to the performance of both tight fitting negative pressure, air-purifying respirators and tight fitting positive pressure respirators. With tight fitting air purifying respirators, a negative pressure is created within the facepiece of a properly fitted respirator when the wearer inhales. A poorly fitted respirator allows contaminated workplace air to enter the facepiece through gaps and leaks in the seal between the face and the facepiece instead of passing through the sorbent material. With tight fitting positive pressure respirators, a poor facepiece fit can result in overbreathing of the respirator with contaminated air leaking into the facepiece. The higher protection levels available with tight fitting positive pressure respirators would be compromised if fit testing were not performed to eliminate poorly fitting respirators.

Where quantitative fit testing is used, the proposal in Appendix E requires that a fit factor of 500 for full facepieces be achieved during the fit test. These fit factor levels are easily obtainable with tight fitting respirators that properly fit the employee. Respirator fit testing is conducted in a laboratory setting, and experience with fit testing has shown that the quantitative fit factors measured in the test booth do not directly translate to those that would be achieved consistently in the workplace. Therefore, the proposal requires that higher fit factors be obtained during quantitative fit testing to better assure that the required levels of protection will be achieved under actual use conditions. Obtaining a proper fit for each employee may require the employer to provide two to three different sizes and types of masks so that an employee can select the most comfortable respirator having a facepiece with the least leakage around the face seal.

Once the proper respirator has been selected, a simple facepiece seal fit check performed at the start of each shift by each employee wearing a tight fitting respirator can meet the objective of demonstrating that a proper facepiece seal is being obtained. This test can be either a positive pressure fit check, in which the exhalation valve is closed and the wearer exhales into the facepiece to produce a positive pressure, or a negative pressure fit check, in which the inlet is closed and the wearer inhales so that the facepiece collapses slightly. Employees must receive training to perform this test properly. In appendix E, Section A (12), OSHA has proposed that the employer maintains records of employee fit testing. OSHA seeks comment on whether having the employee certify the results of a fit test as compared with the record keeping requirements would provide adequate protection to employees who must wear respirators.

As to the protective equipment, the proposal is sufficiently performance-oriented to allow the employer enough flexibility to provide only the protective clothing and equipment necessary to protect employees in each particular work operation from the BD exposure encountered. Therefore, compliance can be tailored to fit the hazards posed on a day-to-day basis.

H. Emergency Situations: Paragraph (h)

Paragraph (h) of OSHA's proposed rule for BD requires that employers develop written plans for emergency situations and that they develop methods of alerting employees of these situations and evacuating workers when necessary. The plan must contain a requirement that employees engaged in correcting an emergency situation be provided with appropriate respiratory protection. Employers would also have to be prepared to alert employees to evacuate the workplace in the event of an emergency. The performance language of the emergency situation paragraph of the standard will give employers the flexibility to choose any effective method of alerting employees, including communications systems, voice communication, or a bell or other alarm.

OSHA is proposing specific provisions for emergency situations because of the potential adverse health effects associated with high BD exposures. The emergency situations that OSHA is concerned about preventing with this provision are those having the potential to produce acute toxic effects among inadvertently exposed employees. The potential acute toxic effects of concern are short-term and reversible effects such as but not limited to frostbite of the skin.

To clarify that the intent of this provision is to protect employees from unexpected and substantial releases of BD, OSHA has defined "Emergency Situations" as "an occurrence such as but not limited to equipment failure, rupture of containers, or failure of

control equipment that may result in an unexpected significant release of BD." The types of emergency situations are those which require securing internal or external emergency services such as rescue, fire, or emergency medical services. OSHA recognizes that not all sudden releases constitute emergencies. For example, the accidental breaking of a sampling syringe containing a minute amount of BD would not normally be regarded as an emergency. On the other hand, failure of a valve on a reaction vessel under pressure, a flange, or a safety relief valve would definitely constitute an emergency.

OSHA believes that these minimal requirements will provide the necessary means to ensure that affected employees are substantially protected against hazardous exposures.

I. Medical surveillance: Paragraph (i)

The purpose of the medical surveillance program for BD is four-fold:

(1) To determine if an individual can be exposed to the concentration of BD present in his or her workplace without experiencing adverse health effects;

(2) To detect, to the extent possible, early or mild clinical conditions due to BD exposure so that appropriate preventative measures can be taken;

(3) To diagnose any occupational diseases that occur as the result of BD exposure; and

(4) To determine the employee's fitness to use respiratory protective equipment.

The proposed requirement for a preplacement examination is intended to achieve, in part, the first objective. This objective is further enhanced by proposing to require that an evaluation of cardiopulmonary system which would include a pulmonary function test be offered to respirator wearers. Moreover, an evaluation of reproductive function can be included if requested by the employee and deemed appropriate by the physician.

The proposed standard requires that each employer institute a medical surveillance program for all employees who are exposed to BD at concentrations at or above the action level for at least 30 days a year, all employees who are or may be exposed to BD at or above the 8-hour TWA or STEL for at least 10 days a year, and all employees exposed to BD in an emergency. Any employee who must wear a respirator is to be offered a medical evaluation of the cardiopulmonary system regardless of the duration of that employee's exposure.

OSHA proposes to require employers to provide medical surveillance to employees who are exposed over the action level for 30 days or more in a year. Employees exposed over the PELs would become eligible for medical surveillance after only 10 days of such exposure. Further, employees required to use respirators are to be offered medical evaluation of their cardiopulmonary system. Including such employees within medical surveillance will provide the greatest benefits. There are at least two advantages to this tiered approach to medical surveillance. First, inclusion of a cut-off based on duration of exposure recognizes that the diseases associated with BD exposure are basically chronic, so that employees exposed for only a few days in a year are likely to be at much lower risk of developing BD-related disease. Employers would be able to focus valuable medical surveillance resources on high-risk employees. OSHA believes that the limits placed on medical surveillance by these cutoffs, based both on exposure level and on the number of days an employee is exposed to BD, are reasonable and represent an administratively convenient way to provide medical surveillance benefits to BD-exposed workers. Second, employees exposed above the PELs must wear respirators. Should the respirator fail or not be worn as prescribed, the employee would be placed at exceptionally high risk. Enhanced surveillance based on level of potential exposure is also a reasonable allocation of scarce medical resources.

OSHA is requiring the employer to provide all employees who will be required to wear a respirator with medical evaluation of their cardiopulmonary function. The examination is to be performed prior to the employee's actual wearing of a respirator and annually thereafter. The purpose of this provision is twofold. First, it allows those individuals who will be exposed above the PELs regardless of the duration of exposure to be at least partially included in the medical surveillance program. Second, respirator usage presents an excess burden to the pulmonary system of the employee. This burden may result in symptoms such as shortness of breath, chest pain, dizziness or fatigue. All of these symptoms will be greatly exacerbated by pre-existing lung disease such as chronic bronchitis, emphysema, asthma or pneumoconiosis. It is, therefore, imperative that all employees who will be wearing respirators be medically monitored to determine fitness for respirator usage. OSHA believes that the physician can best accomplish this through administering an examination of the cardiopulmonary function.

The medical examinations for emergency situations are not triggered by airborne concentrations routinely found in a workplace. Where very large amounts of materials are kept in a sealed system, routine exposure may be essentially zero. However, rupture of the container might result in catastrophy. Thus, employers who have identified that they have operations where there is a potential for an emergency involving BD must take necessary actions to assure that, in the event an emergency occurs, facilities will be available and medical assistance by professionals knowledgeable about the toxic effects of BD will be rendered to exposure victims promptly.

The OSH Act requires that, where appropriate, occupational health standards shall prescribe the type and frequency of medical exams or other tests to be made available by the employer or at his or her cost to exposed employees in order to determine if the employee's health is adversely affected by his or her exposure. All medical procedures would have to be performed by or under the supervision of a licensed physician, and the medical surveillance would have to be offered at a reasonable time and place and without cost to employees.

Medical examinations would be provided to employees before their initial assignment to work in an area where they would be exposed to BD, annually thereafter, and upon termination of employment or reassignment to an area where they are no longer being exposed to BD at airborne levels at or exceeding the action level. OSHA's requirement for a preplacement examination is intended to achieve the objective of determining if an individual will be able to work with the given BD exposure without adverse effects. It also serves the useful function of establishing a general health baseline for future reference.

Annual medical surveillance would emphasize the occupational and medical history of the worker and the physical examination conducted by the physician. A complete blood count would also be required. Employees with special needs, i.e. those who have special reproductive concerns or hematopoietic or reticuloendothelial changes of an unknown nature, would have to be offered medical examinations adequate to permit the responsible physician to determine whether or not their health is being impaired by BD exposure.

Employers would be required to provide the responsible physician with the information needed to assure that the physician will be adequately informed to reach a medical determination including the employee's duties, exposures and protective equipment worn, if any. The physician would be required to provide a written determination to the employer. The employee would be informed of all results of his or her medical examination including diseases of a nonoccupational origin.

The health hazards known or suspected to be associated with occupational exposure to BD consist of non-Hodgkins lymphoma, leukemia, adverse reproductive and developmental outcomes in males and females and their offspring, and anemia. Most of this information is derived from toxicology studies in rats and mice. Epidemiologic studies revealed suggestive evidence consistent with the results found in animals.

Evidence in animals suggests that BD is capable of adversely affecting the reproductive organs in males and females as well as causing developmental problems in the offspring of exposed dams. BD as a reproductive toxin has not been examined in humans. BD's capability to cause cancer in animals at multiple sites, however, coupled with its potential to be metabolized to toxic intermediates that are capable of binding to DNA, suggests that this chemical may interact with germ cells as well as somatic cells. Thus, BD should be regarded as a possible reproductive and developmental toxic agent in humans; the no-observed-effect-level (NOEL) for humans is essentially unknown although animal evidence suggests that it is below the current permissible exposure limit.

Alterations in the peripheral blood cells are not especially characteristic of lymphomas (Exs. 23–52, 23–57). The correlation between peripheral blood counts and marrow involvement by lymphoma is poor. Some abnormality in blood counts is found in only 37 percent of patients with bone marrow infiltration. Examination of the peripheral smear in patients with non-Hodgkins lymphoma may yield evidence of malignant cells in about 15 percent of patients (Ex. 23–52, p. 1,357). Changes in hemoglobin level (Hgb), thrombocyte (platelet) count, and leukocyte count do occur in the presence of leukemia. Furthermore, anemia has been observed in mice exposed to BD for too short a time interval for the expression of neoplasia, and blood cell changes, not necessarily indicative of bone marrow involvement, have also been observed in workers exposed to BD. Thus, in deciding to include a complete blood count (CBC) in the proposed medical examinations, OSHA gave weight to the possibility that BD may be associated with leukemia and anemia as well as non-Hodgkins lymphoma.

The main goal of periodic medical surveillance for workers should be to detect adverse effects at an early, and potentially still reversible stage. In general, this goal is difficult to achieve for cancer which is not a readily reversible disease, although the prognosis is better for patients in the earlier stages of the disease. Some types of leukemia and lymphoma, unlike carcinomas, remain curable even at an advanced stage (Ex. 23–49). Consequently, periodic medical surveillance for BD can achieve the goal of detecting early bone marrow toxicity.

While the medical surveillance program proposed cannot detect BD induced cancer at a preneoplastic stage, OSHA anticipates that, as in the past, methods for early detection and treatments leading to enhanced survival rates will continue to evolve. Additionally, current knowledge of the diseases that may be caused by BD is far from complete; for some effects, such as anemia and reproductive toxicity, it is not possible to determine with quantitative certainty the level of protection afforded the worker by the proposed standard. It is also not presently possible to identify all diseases that may be associated with exposure to BD nor to demonstrate that changes in the blood are markers that identify persons at high risk of subsequently developing cancer from their exposure to BD. Thus, an important goal of the medical surveillance program is to provide information on the adequacy of the proposed PELs for BD.

Consistent with other recently promulgated standards including Benzene (29 CFR 1910.1028) and Formaldehyde (29 CFR 1910.1048), OSHA is proposing that all medical procedures be performed by or under the supervision of a licensed physician. Clearly, a licensed physician is the appropriate person to supervise and evaluate a medical examination. However, certain parts of the required examination do not necessarily require the physician's expertise and these may be conducted by other suitably qualified health care personnel under the supervision of the licensed physician.

The proposed requirement that examinations are to be offered without cost to the employee and be given at a reasonable time and place and without loss of pay is necessary to ensure that employees will participate in the medical surveillance program. This provision is also consistent with other OSHA health standards and with provisions contained in the OSH Act.

OSHA is proposing to require that persons, other than licensed physicians, who administer the pulmonary function tests required by the BD proposal, must complete a training course in spirometry sponsored by an appropriate governmental, academic, or professional institution. This provision is consistent with several other OSHA standards, including Cotton Dust (50 FR 51220) and Benzene (29 CFR 1910.1028), and it will assure that the numerous BD employees who must wear respiratory protection will receive adequate assessment of their lung capacity, a vital test in determining if they are capable of wearing respirators.

The proposed medical surveillance program specifies when employees must be offered medical examinations and consultations. Routine screening, which includes occupational and medical histories, physical examinations, and examinations of the peripheral blood cells, must be offered annually for all employees eligible to participate. The interval proposed is consistent with other OSHA health standards; based on OSHA's experience with these other standards, the Agency believes that annual surveillance would strike a proper balance between the need to diagnose leukemias or lymphomas at an early stage to enhance the possibility of remission through medical intervention and the limited number of cases likely to be identified through the surveillance program. There is no fixed interval for examinations provided following exposure in an emergency. These events do not occur at any established interval; they are a matter of individual concern.

The purpose of the periodic examination is to detect individuals with blood changes characteristic of anemia, or leukemia, and to detect, by physical examination, any individuals with non-Hodgkins lymphoma. To achieve these goals, the health status of each employee must be reviewed periodically when there is a likelihood that workplace exposures or activities could produce these adverse effects. Because leukemias and lymphomas can occur after a relatively short latency period, OSHA has proposed to make annual surveillance available to all employees regardless of their age or length of employment in a BD exposure area.

To assure that no employee terminates employment while carrying an active, but undiagnosed, disease, OSHA is proposing to require that the employer offer a medical examination to employees when they terminate their employment in the BD area or transfer to an area where they would no longer remain eligible for future surveillance. OSHA has some concern that this may not be wholly adequate for identifying cancer in high risk employees and requests public comment on whether continued annual surveillance should be offered to employees who have transferred to other areas within the corporation.

Predisposition to lymphomas is associated with immune deficiency syndromes. In addition, leukemia has been associated with benzene exposure; ionizing radiation; and certain drugs, which can cause aplastic anemia. An adequate patient history would collect information on the patient's potential or past exposure to such substances to aid in identification of employees at highest risk and to determine if other factors, as well as BD, might be involved.

Non-Hodgkins lymphoma and leukemia often cause charactristic complaints in patients. Not infrequently the signs and symptoms are sub-clinical. Therefore it is extremely important that a thorough medical and occupational history be taken for these workers followed by a thorough physical examination as the second step.

Animal evidence suggests that BD affects the bone marrow, resulting in anemia. In mice, inhalation of BD at 1,250 ppm resulted in a decrease in circulating erythrocytes, total Hgb and hematocrit (Hct), an increase in mean corpuscular volume, and leukopenia, due mainly to a decrease in segmented neutrophiles (Ex. 23–12). These findings would be inconsistent with a diagnosis of macrocytic megaloblastic anemia suggesting that a complete blood count (CBC) with a leukocyte count might yield information on over exposure to BD at such a time that the toxic effects would be reversible. Consequently, OSHA has proposed to require a CBC for preplacement and periodic medical examinations for all workers exposed to BD at concentrations exceeding the action level for the time periods specified. A CBC would consist of a white blood cell count (WBC), Hct, Hgb, differential count, red blood cell count (RBC) and WBC and RBC morphology (Ex. 23–55).

The specific diagnosis of lymphoma or leukemia is not simple. If physical examination reveals characteristic signs, additional confidence in the possible diagnosis can be made by obtaining relevant laboratory tests. However, for a definitive diagnosis, additional examinations would need to be performed by an experienced hematologist; the assistance of other specialists may be necessary also (Exs. 23–52, 23–57). Furthermore, prompt diagnosis is considered essential to the medical management of the patient. Consequently, OSHA is requiring the employer to cover the cost of specialists called in by the attending physician when there are abnormalities of the hematopoietic or reticuloendothelial systems for which no cause can be found. OHSA considers this proposed requirement essential to ensure that employees receive prompt diagnosis at the earliest stage possible so that the treatments needed to effect remission of cancer will be more likely to succeed.

The extent and the type of service to be made available to employees who are concerned about their reproductive health will be determined by the examining physician so that affected employees can benefit from new technologic developments and the responsible physician can provide services appropriate to the risk to the concerned individual. In extreme circumstances, the physician might recommend evaluation of fertility should the employee be exposed to substantial amounts of BD from a leak or spill and should the employee request such tests.

In contrast to the chronic toxicity of BD, the acute effects of BD would be described as practially nontoxic based on LD_{50} studies even though sensory irritation and narcosis are possible at very high doses (see ratings in appendix A of the Hazard Communication Standard, 29 CFR 1910.1200). In fact, the upper level of testing in animals has been capped by the necessity of keeping the exposures below the lower explosion limit. Thus, medical monitoring proposed for employees exposed to BD at high concentrations in emergencies focuses on the possibility that there is a dose rate effect which makes the potential for long-term consequences more severe than if the same integrated dose were received over a period of years. In addition, there is a possibility that a more acute form of neoplasia, with a short latency period, might occur. Of course, any acute effects seen in an employee exposed to BD in an emergency should be treated.

To ensure that the responsible physician has the information needed to perform an assessment of the patient's ability to work with BD, OSHA is proposing that the employer provide the responsible physican with a copy of the standard and all relevant appendices. For the same reasons, the employer would also have to supply the responsible physician with information from previous medical examinations that were administered to the employee and that are under the employer's control.

OSHA proposes to require employers to supply the results of exposure monitoring and information on any personal protective equipment and respiratory protection used or to be used by the employee to the physician responsible for medical surveillance. For emergencies, the employer would be required to supply the physician with a description of the details surrounding the emergency. This information would assist the physician in determining if an employee is likely to be at risk of harmful effects from BD exposure. A well-documented exposure history also assists the physician can in determining if a disease that is observed may be related to BD exposure, and it helps the physician to determine if any restrictions should be placed on the employee's occupational exposure to BD based on medical findings.

The proposal would require employers to obtain from the examining physician a written opinion containing the results of the medical examination, the physician's opinion as to whether the employee would be placed at increased risk of material health impairment as a result of exposure to BD, and any recommended limitations on the employee's exposure or use of personal protective equipment. In rendering his opinion regarding the employee's suitability for work with BD, the physician must rely on the obtained results of clinical and other tests performed to support his or her conclusions.

The physician must exclude findings or diagnoses which are unrelated to occupational exposure in the written opinion to reassure employees participating in medical surveillance that they will not be penalized or embarrassed by the employer's obtaining information about them not directly pertient to BD exposure. Such findings, however, should be communicated to the employee directly.

Employers are required to retain the records of the results of the medical examination an any tests performed, and they would have to provide a copy of the physician's written opinion to the employee within 15 days of receiving the opinion to ensure that the employee has been informed of the results of the medical examination in a timely manner. This medical surveillance program would protect employees and it would be a cost-effective approach to

identifying employees whose health may be adversely affected by exposure to BD.

The medical surveillance program proposed for BD is not expected to yield a large number of diagnosed cancers compared with the number of employees screened. Combined, lymphomas and leukemias account for only 9 percent of all cancers (Ex. 23–49), and the number of cases that should be found in an actively employed group of workers would be low. Nevertheless, the development of cancer is an extremely serious material impairment of health. For non-Hodgkins lymphoma, approximately half of the diagnosed cases are fatal within five years; for those who survive, extensive medical intervention is mandatory.

Consequently, OSHA has determined that the gravity of the diseases potentially caused by exposure to BD are sufficient to warrant a medical surveillance program that will be highly sensitive to the need to detect those employees who are at highest risk.

Evidence that BD is a carcinogen in animals is based on studies in which two species developed multiple site carcinogenicity following BD exposure. Malignancies at numerous sites were seen in rats and mice however, suggesting that humans may also be at risk of developing types of tumors other than lymphoma or leukemia from their exposure to BD.

It is possible, as suggested by the animal evidence, that the bone marrow is not the only site of carcinogenic action of BD or its metabolities in humans. If this is the case, other organs may also be targets for carcinogenic expression. Information available is not adequate to identify these sites at this time, and OSHA has not focused on any strategies for prevention of cancer at sites other than the lymphatic or hematopoietic systems in the proposed medical surveillance. Should such information become available during the course of these proceedings or at a later date, the responsible physician may expand the medical surveillance provided to workers to include appropriate testing.

OSHA is considering the possibility of expanding the proposed medical surveillance to include workers who were formerly exposed to BD in previous jobs while working for the same employer. Becaue cancer rates increase rapidly with age and because long-term workers were exposed to BD while open systems or batch processes were in use, inclusion of such persons should greatly enhance the number of cases of cancer of the hematopoietic and reticuloendothelial systems identified by the medical surveillance program. Such an approach would be consistent with the requirement in the Benzene standard (29 CFR 1910.1028) which makes medical surveillance available to employees who have been exposed to greater than 10 ppm of benzene (the former standard) for 30 or more days in a year prior to the effective date of the standard when such exposures occurred while the employee worked for his or her current employer. OSHA is seeking comments from the public on whether an expanded medical surveillance program should be included in the final rule and any limitations that should be imposed on participation in such a program.

OSHA is also considering the appropriateness of providing Medical Removal Protection (MRP) with pay rate retention, as outlined in the Lead Standard, for any employee whose medical examination indicates that further testing by specialists is needed to confirm whether or not abnormal adverse health effects related to BD exposure are present. It would be anticipated that the MRP would be extended for short periods only given the urgency of the follow-up tests for a person whose health may be impaired. Therefore OSHA also seeks comments on the need for such a provision and the elements that should be included if MRP is adopted in the final rule for BD.

J. Communication of BD Hazards to Employees: Paragraph (j)

In this proposed BD standard, OSHA includes a paragraph entitled: "Communication of BD hazards to employees." This paragraph addresses the issue of transmitting information to employees about the hazards of BD through the use of: (1) Signs and labels, (2) material safety data sheets, and (3) information and training. Previous OSHA health standards generally included separate paragraphs on employee information and training and signs and labels. This standard incorporates both of those areas into this single paragraph, consistent with the intent of the generic standard, Hazards Communication (29 CFR 1910.1200) which addresses all three items as essential to the purpose of informing workers of the hazards of the chemicals they use in their workplace.

On November 25, 1983, the Occupational Safety and Health Administration published its final rule on Hazard Communication at 48 FR 53280 and 52 FR 31852 (29 CFR 12919.1200). The Hazard Communication Standard (HCS) requries all chemical manufacturers and importers to assess the hazards of the chemical which they produce or import, and all employers to provide information concerning the hazards of such chemicals to their employees. The transmittal of hazard information to employees is to be accomplished by means of comprehensive hazard communication programs, which are to include container labeling and other forms of warning, material safety data sheets and employee training.

Since the HCS "is intended to address comprehensively the issue of evaluating the potential hazard of chemicals and communicating information concerning hazards and appropriate protective measures to employees" [52 FR 31877], OSHA proposes this new paragraph entitled "Communication of BD Hazards to Employees" to avoid repetition of those requirements now comprehensively laid out in § 1910.1200 while specifying additional particular requirements that are needed to protect employees exposed to BD. While avoiding a duplicative administrative burden on those employers attempting to comply with the requirements of several different applicable OSHA health standards, the proposed requirements nevertheless provide the necessary protection for employees through provisions for signs and labels, material safety data sheets, and employee information and training. It should be noted that the communication of BD hazards paragraph of the BD standard has been designed to be substantively as consistent as possible with the HCS requirements for employers. The HCS also addresses the responsibility of producers of chemicals to provide information to downstream employers.

The proposed standard requires that regulated areas be posted with signs stating: "Danger, 1,3-Butadiene, Potential Cancer and Reproductive Hazard, Can Cause Lung and Kidney Damage, Authorized Personnel Only, Respirators and Protective Clothing Required in this Area". The proposed standard intends that the posting of these signs will serve as a warning to employees who may otherwise not know they are entering a regulated area. Such warning signs are required to be posted whenever a regulated area exists, that is, whenever the permissible exposure limit is exceeded. For some work sites, regulated areas exist as a permanent situation, because there is an area where exposures cannot be reduced below the PEL by the use of engineering controls. In those situations, the signs are needed to warn employees not to enter the area unless they are authorized, wearing respirators, and

unless there is a need for entering the area.

Regulated areas may also exist on a temporary basis, such as during maintenance and/or emergency situations. The use of warning signs in these types of situations is also important, since a maintenance or emergency situation is by nature a new or unexpected exposure to employees who are regularly scheduled to work at these sites.

These signs are intended to supplement the training which employees are to receive under the other provisions of this paragraph, since even trained employees need to be reminded of the locations of regulated areas and of the precautions necessary to be taken before entering these dangerous areas.

The proposed standard specifies the wording of the warning signs for regulated areas in order to ensure that the proper warning is given to employees. OSHA believes that the use of the word "Danger" is appropriate, based on the evidence of the toxicity and carcinogenicity of BD. "Danger" is used to attract the attention of workers, to alert them to the fact that they are in an area where the permissible exposure limit is exceeded, and to emphasize the importance of the message that follows. The use of the word "Danger" is also consistent with other recent OSHA health standards dealing with carcinogens. The proposed standard also requires that the legend, "Respirators Required in this Area", be included on the warning sign. While OSHA recognizes that some employees entering the regulated areas may not be exposed above either the 8-hour PEL of 2 ppm or the STEL of 10 ppm as averaged over a 15-minute period, it is still possible that many employees who are assigned to work in these areas may remain in these locations for long enough periods of time so that they would be needlessly overexposed to BD without the use of respirators and protective clothing. To ensure that these employees are adequately protected, it is necessary that the sign alert them to the need to wear respirators and protective clothing.

The proposal also requires that warning labels be affixed to all shipping and storage containers containing BD. The labels must state: "Danger, Contains 1,3-Butadiene, Potential Cancer and Reproductive Hazard". It is proposed that required labels would remain affixed to containers leaving the workplace. The purpose of this requirement is to ensure that all affected employees, not only those of a particular employer, are apprised of the hazardous nature of BD exposure where exposure could exceed the action level.

In addition to being consistent with the requirements of the HCS, these requirements are consistent with the mandate of section 6(b)(7) of the Act, which requires OSHA health standards to prescribe the use of labels or other appropriate forms of warning to apprise employees of the hazards to which they are exposed.

OSHA also proposes in this BD standard to require the employer to obtain or develop and to distribute and provide access to a material safety data sheet for BD in accordance with the requirements of 29 CFR 1910.1200(g). OSHA feels that a properly completed material safety data sheet (MSDS), if readily available to employees, can serve as an excellent, concise source of information regarding the hazards associated with BD. OSHA's primary intent in this section of the proposed standard, as stated in its recently promulgated HCS, is to ensure that employees will receive as much information as is needed concerning the hazards posed by chemicals in their workplaces. The material safety data sheet ensures that this information will be available to them in a usable, readily accessible and concise form. The material safety data sheet also serves as the central source of information to employees and downstream employers who must be provided with an MSDS if BD or a product containing BD is produced and shipped out of the plant. In addition, the MSDS serves as the basic source of information on the hazards of BD essential to the training provisions of this and other applicable health standards.

Producers and importers have the primary responsibility, under the HCS to develop or prepare the material safety data sheet. The manufacturer or importer is most likely to have the best access to information about the product, and is therefore responsible for disseminating this information to downstream users of the material. For employers whose employees' exposure to BD is from products received from outside sources, the information necessary in producing MSDS or the MSDS itself is to be obtained from the manufacturer and made available to affected employees. The requirements for the information that is to be contained on the material safety data sheet are explained in detail at 29 CFR 1910.1200(g).

Paragraph (j)(4) of this proposed BD standard requires employers to provide all employees who are exposed to BD with information and training on BD at the time of initial assignment and at least annually thereafter. A record shall be maintained of the contents of such programs. The training program is to be in accordance with the requirements of the HCS paragraphs (h)(1) and (2), including specific information required to be provided by that section and those items stipulated in Section XIV paragraph (j)(4)(iii) of this standard. In addition, employees are to be provided with an explanation of the contents of Appendices A (Substance Safety Data Sheet, BD) and B (Substance Technical Guidelines, BD) of the BD standard. Employees are to be informed where a copy of the BD standard is accessible to them, and receive a description of the medical surveillance program required under paragraph (l) of this proposed standard. Employees are also to receive an explanation of the purpose of paragraph (l), medical surveillance program, for BD.

OSHA has determined during other rulemakings that an information and training program, as incorporated in this proposed standard in an overall "Communication of BD Hazards to Employees" paragraph, is essential to inform employees of the hazards to which they are exposed and to provide employees with the necessary understanding of the degree to which they themselves can minimize the health hazard potential. As part of an overall communication program for employees, training serves to explain and reinforce the information presented to employees on labels and material safety data sheets. These written forms of information and warning will be successful and relevant only when employees understand the information presented and are aware of the actions to be taken to avoid or minimize exposures thereby reducing the possibility of experiencing adverse health effects. Training is essential to an effective overall hazard communication program. Active employee participation in training sessions can result in the effective communication of hazard information to employees which can further result in workers taking conscientious protective actions at their job duties, thereby decreasing the possibility of occupationally-related illnesses and injuries.

OSHA proposes the training provisions of this standard to be in performance-oriented, rather than specified and detailed language. The proposed standard, in requiring training to be in accordance with the requirements of 29 CFR 1910.1200, lists the categories of information to be transmitted to employees and not the

specific ways that this is to be accomplished. The use of such performance-oriented requirements will encourage employers to tailor their training needs to their specific workplaces, thereby resulting in the most effective training program suitable for each specific workplace.

OSHA believes that the employer is in the best position to determine how the training he or she is providing is being received and absorbed by the employees. OSHA has, therefore, described the objectives to be met and the intent of its training to ensure they can help to protect themselves. The specifics of how this is to be accomplished are left up to the employer.

K. Recordkeeping: Paragraph (k)

Section 8(c)(3) of the Act provides for the promulgation of "regulations requiring employers to maintain accurate records of employee exposures to potentially toxic materials or harmful physical agents which are required to be monitored or measured under section 6." The proposed standard would require that employers who rely on objective data in order to gain exemption from the proposed monitoring requirements maintain records that show that basis and reasoning used in reaching the conclusion that the employer should be exempted. In this respect, the objective data substitute for the initial monitoring requirements and the requirement to maintain a record protects the employer at later dates from the contention that an initial monitoring was not conducted.

The proposed rule would require that employers keep records to identify the employee monitored and to accurately reflect each employee's exposure. The proposal would also require that the employer keep accurate medical records for each employee subject to medical surveillance. Section 8(c) of the Act authorizes the promulgation of regulations requiring an employer to keep necessary and appropriate records regarding activities to permit the enforcement of the Act or to develop information regarding the causes and prevention of occupational illnesses. OSHA has determined that, in this context, requiring employers to maintain both medical and exposure records (including pulmonary function test results related to respirator use and initial determinations or justifications of exemption from monitoring) is necessary and appropriate. In addition, medical records are necessary for the proper evaluation of the employee's health. Since there is no useful purpose served in long term retention of respirator fit test results, OSHA has proposed to require keeping these test results only until the next fit testing.

The proposed standard would require that all required records be made available upon request to the Assistant Secretary and Director of NIOSH for examination and copying. Access to these records would be necessary for OSHA to monitor compliance. These records also contain information which either of the agencies may need to carry out other statutory responsibilities.

The proposed rule would provide that employees, former employees, and their designated representatives would have access to exposure determinations and records upon request. Section 8(c) (3) of the Act explicitly provides for the promulgations of regulations to "provide employees or their representatives with an opportunity to observe such monitoring or measuring and to have access to the records thereof." Several other provisions of the Act contemplate that employees and their representatives are entitled to have an active role in the enforcement of the Act. Employees and their representatives need the pertinent information concerning exposures to toxic substances and the consequences for the health and safety of the employees if they are to benefit fully from these statutorily created rights.

In addition, the proposal specifies that access to exposures and medical records by employees, designated representatives, and OSHA shall be provided in accordance with 29 CFR 1910.20. OSHA promulgated 29 CFR 1910.20 as the generic rule for access to employee exposure and medical records on May 23, 1980 (45 FR 35212). It applies to records created pursuant to specific standards and to records which are voluntarily created by employers. OSHA retains unrestricted access to medical and exposure records but its access to personally identifiable records is subject to the Agency's rules of practice and procedure concerning OSHA access to employee medical records, which have been published at 29 CFR 1913.10. An extensive discussion of the provisions and the rationale for § 1910.20 may be found at 45 FR 35312. The discussion of § 1913.20 may be found at 45 FR 35384. It is noted that revisions to the access to records standard are being developed in an ongoing rulemaking proceedings. The BD standard may be affected by any changes which result from the rulemaking effort.

It is necessary to keep records for extended periods of time because of the long latency periods commonly observed for the induction of cancer caused by exposures to carcinogens. Cancer generally cannot be detected until 20 or more years after onset of exposure. The extended record retention period is therefore needed for two purposes. First, possession of past and present exposure data and medical records furthers the diagnosis of workers' ailments. In addition, retaining records for extended periods makes possible a review at some future date of the effectiveness and adequacy of the proposed standard.

The time periods required for retention of exposure records and medical records would be thirty years and the period of employment plus thirty years, respectively. These retention requirements would be consistent with those in the OSHA records access standard and with pertinent sections of the Toxic Substances Control Act.

The proposed standard would require employers who are going out of business without a successor to notify the Director of NIOSH in writing at least 90 days prior to the disposal of records and to transmit them to NIOSH unless told not to do so by NIOSH. The employer would be required to comply with any other applicable requirements set forth in the records retention standard.

L. Observation of monitoring: Paragraph (l)

Section 8(c) (3) of the Act requires that employers provide employees and their representatives with the opportunity to observe monitoring of employee exposures to toxic substances or harmful physical agents. In accordance with this section, the proposal contains provisions for such observation of monitoring of BD exposures.

The observer, whether an employee or a designated representative, must be provided with, and is required to use, any personal protective equipment required to be worn by employees working in the area that is being monitored, and must comply with all other applicable safety and health procedures.

M. Date: Paragraph (m)

As proposed, the final rule would become effective sixty (60) days following publication in the **Federal Register**. OSHA requests comment on whether additional time should be provided. The Agency also solicits information and supporting data on "start-up periods" and delayed implementation dates which may be necessary for various provisions of the standard.

N. Appendices: Paragraph (n)

Five appendices have been included in this proposal standard. These appendices have been included primarily for purposes of information. None of the statements contained therein should be construed as establishing a mandatory requirement not otherwise imposed by the standards, or as detracting from an obligation which the standard does impose.

The information contained in Appendices A and B is designed to aid the employer in complying with requirements of the standard. The information in Appendix C primarily provides information needed by the physician to evaluate the results of the medical examination. It should be noted that paragraph (i) specifically requires that the information contained in Appendices A and B be provided to employees as part of their information and training program.

Appendix D gives details of the OSHA sampling method for use in monitoring employee exposures to BD. Appendix E is the "Qualitative and Quantitative Fit Testing Procedures."

XII. Environmental Impact:

OSHA has reviewed the proposed standard for BD and concluded that no significant environmental impact is likely to occur from promulgation of a new standard.

On October 1, 1986, OSHA published an Advanced Notice of Public Rulemaking (ANPR) to initiate rulemaking within the meaning of section 9(a) of TSCA for occupational exposure to BD. Information and comments were solicited from the public on a variety of issues (including environmental impacts) surrounding the promulgation of a new standard. The information and comments received in response to the ANPR have been reviewed in accordance with the requirements of the National Environmental Policy Act (NEPA) of 1969 (42 U.S.C. 4321, et seq.), the Council of Environmental Quality (CEQ) (40 CFR part 1500), and OSHA's DOL NEPA Procedures (29 CFR part 11). As a consequence of this review, the Assistant Secretary has determined that the proposed rule will not have a significant impact on the environment external to the workplace.

BD is a high-volume chemical used primarily in the manufacture of synthetic rubbers through the process of polymerization. The new standard for this chemical can be achieved through a combination of engineering controls, work practices, and respirator use on the part of the crude, monomer, and polymer sectors of the BD industry.

OSHA believes that the controls that are optimal, from a cost minimizing and worker safety point of view, will have no significant adverse impact on the external environment because (1) no additional solid waste would be contaminated with BD and (2) any new release to the external atmosphere would constitute an insignificant increase in emissions. Indeed, several of the recommended controls would prove to be advantageous from an environmental point of view. For example, under current practice, rail tank cars (used for transport of crude C^4 streams as well as for delivery of BD product) are often fitted with slip-tube gauges. While this monitoring system requires less individual attention than alternatives such as magnetic gauges, it also has the potential for direct release of BD to the atmosphere as well as to the breathing area. The proposed standard will encourage firms to use magnetic gauges because such gauges operate without the release of vapor into the atmosphere and thereby provide better protection for individuals at risk. Similarly, implementation of leak detection programs and the use of closed loop sampling techniques by industry personnel engaged in analysis and quality control, should provide better protection for both workers and the external environment.

Other engineering and non-engineering controls, such as enclosed vacuum exhaust vents in laboratories for cylinder voiding and increased respirator use, involve circumstances in which environmental emissions of BD remain constant, or, else, no causal link exists between implementation of the control and impact on the external environment.

Although transportation of BD presents the potential for leaks or spills, such contingencies are viewed as effects of events unrelated to implementation of the new standard, and under the jurisdiction and authority of the Department of Transportation.

Based on this discussion and other information presented in this proposal, OSHA concludes that there will be no significant impact on the environment external to the workplace as a consequence of the promulgation of a new standard for BD. OSHA, of course, reserves the right to perform additional environmental analyses as a consequence of the information and comments received in response to this proposal.

XIII. Request for Information and Comments

Public comment on the data discussed in this Notice and other relevant issues is requested for the purpose of assisting OSHA in its evaluation of the adequacy of the present standard and the development of a revised standard for exposure to BD. OSHA also requests that interested parties submit any pertinent health data not discussed in this notice.

Comment is requested on the following issues relating to health effects, technological and economic feasibility, and provisions which should be considered for inclusion in a final BD standard. Specifically, scientific and technical data and expert analysis and opinion are sought on the following issues:

1. Do the proposed provisions provide adequate protection for workers against all known health hazards associated with exposure to BD?

2. Does OSHA's proposed STEL of 10 ppm for BD reduce worker exposure over and above the reduction provided by the PEL? OSHA has stated that the health evidence for BD indicates that the occurence of a dose-rate effect, provides further justification for the STEL. Are there comments on OSHA's assessment? Should other short-term exposure limits be considered?

3. Are there additional or updated epidemiological studies or updated information on exposures for the cohorts comprising the studies OSHA has included in this proposal that would be useful to the Agency in assessing the risk of occupational exposure to BD?

4. Please provide any additional information that OSHA should consider in developing its estimates of risk. OSHA is especially interested in receiving information on how BD has affected employee sickness, absences, productivity, and the concentrations at which such effects occur.

5. What is the lowest feasible level of exposure achievable by engineering controls and work practices? For example, can BD exposures be reduced by available technologies to levels below the proposed 2 ppm PEL.

6. OSHA solicits comments on the statistical analytical methodology determining the feasibility of the proposed PELs. In this approach the PELs are assumed to be feasible if, after the addition of a control measure, at least 95% of the occupational group is found to be at or below the PELs. In addition, OSHA's analysis assumed that respirators would be used by all members of a given occupational group

whenever the probability of exposure above the PELs. for that group was greater than 5%.

7. OSHA has proposed that all employees who must wear a respirator but do not meet the 10-day minimum exposure requirement for inclusion in medical surveillance be offered at least a cardiopulmonary examination that includes a pulmonary function test. Is this appropriate or should this group of respirator wearers' (i.e. those exposed above the PELs between 1and 9 days each year) eligibility for the cardiopulmonary system evaluation be subject to a certain minimum exposure period? If so, what should that exposure period be?

8. Should OSHA adopt the respiratory protection provisions contained in the proposed Methods of Compliance standard (54 FR 23991) instead of the current language in the BD Proposal? If so, are there modifications that would need to be made in the provision of that proposed standard in order to provide appropriate protection against exposures to this specific substance?

9. The methods of compliance proposal does not require employers to institute all feasible engineering controls when only a negligible reduction in exposure is thereby achieved. Instead of using "negligible reduction" as the cut-off-point, should OSHA quantify the boundaries of exposure reduction and subsequent attainment level? If quantifiable boundaries of exposure reduction are included, should they take into consideration only health concerns or should they also incorporate safety hazards (e.g. flamability, explosivity)?

10. Please provide any additional information on feasible engineering and work practice controls that would lower workers exposure to 2 ppm or lower levels? Please include the cost and time necessary for their implementation.

11. Are there any unique conditions in work settings where BD is produced or used where engineering controls are not available or feasible?

12. What are the technological modifications in the production or use of BD for the purpose of improving productivity or product quality which have also resulted in changes (reductions or increases) in BD exposures?

13. Is Medical Removal Protection (MRP) beneficial for employees due to the risk of material impairment to health and what should these provisions be? Please provide information and data supporting your views.

14. Are all the medical tests specified in this rulemaking appropriate for enhancing early detection of adverse health effects resulting from BD exposure? If not, please identify those regarded to be inappropriate and give the specifics of the reasons.

15. What additional provisions for medical surveillance should be included? What kind of clinical tests should be offered to employees exposed in emergency situations?

16. Does the coverage of employees under medical surveillance include all employees whose exposures warrant coverage? If not, how should the coverage be expanded? If the present requirements for inclusion are retained, how much of the total BD-exposed workforce will be eligible to participate?

17. Please provide information supporting the inclusion of provisions for medical examinations, respirators, personal protective clothing and equipment, hygiene facilities and practices, emergencies, regulated areas, maintenance of records, housekeeping, employee information and training, and labels and signs? What form should such provisions take in the final standard? To what extent are these provisions currently being employed by industry and what are their costs?

18. Are there conditions under which respirator use should be permitted in addition to those proposed? Can employees who wear negative pressure respirators be adequately protected without quantitative fit testing? What specific limits should be placed on canister and cartridge lives? Please provide additional information on breakthrough time of various respirators.

19. What measurement and analytical methods are available for use in determining compliance with the BD proposed PEL of 2 ppm or the 1 ppm action level? Can these methods measure the proposed STEL of 10 ppm? How accurate are these methods? Are there any special conditions for sample collection and preservation that should be included in the final standard so that reliable results can be obtained?

20. Should work places relying on objective data to document the fact that employees are not exposed at or above the action level be required to install alarm devices sensitive to concentrations at or below the action level? Are passive diffusion devices reliable to detect short term exposure of employees to BD? Can they detect levels as low as 1 ppm?

21. What are the numbers of workers exposed to BD, their current exposure levels, the methods of monitoring used to measure these exposures, duration and frequency of exposure, the duties being performed, and the Standard Industrial Classification (SIC) Codes for industries and processes handling BD?

22. Should the standard include specific provisions prohibiting activities that are known to result in excessive exposures such as, but not limited to, open loop sampling? Should the standard include provisions specifying controls that are known or proven to be effective in reducing workers' exposure such as but not limited to the use of tandem seal in pumps?

23. Has OSHA accurately estimated all costs associated with achieving compliance with the proposed new rule? Are those costs economically feasible for the affected industries? How would the time allowed to install these engineering controls affect these costs?

24. The BD record includes copies of the Regulatory Impact Analysis and the JACA report. Comments are requested on those analyses, the feasibility and the cost-effectiveness of the proposed standard and alternatives.

25. OSHA is requesting public comments on the feasibility and cost effectiveness of the two monitoring methods, leak detection and continuous monitoring, as well as any other feasible methods. Leak detection and continuous monitoring are discussed above in the Technological Feasibility section of the Summary of Preliminary Regulatory Impact and Regulatory Flexibility Analysis and in the Methods of Compliance section of the Summary and Explanation of the Proposed Standard .

26. In order to perform an economic feasibility analysis, it is helpful to have a financial and economic profile of the industries producing and using BD. Information is requested to aid in the preparation of that profile. Data should be provided for the last five years.

27. How does the proposed standard affect industry's economic position, particularly with regard to foreign import competition in the domestic U.S. market, and the price of U.S. goods for export?

28. The Agency has prepared a draft Regulatory Flexibility Analysis analyzing the impacts of the proposed standard on the small businesses which OSHA believes may be affected and adapting the proposed standard to take into account the circumstances of small business where appropriate. The following information is requested for small businesses in addition to the information OSHA has gathered.

(a) What kinds of small businesses or organizations and how many of them would be affected by regulating exposures to BD?

(b) Which, if any, federal rules may duplicate, overlap, or conflict with an OSHA regulation concerning BD?

(c) Will difficulties be encountered by small entities when attempting to comply with requirements of the proposed standard? Can some of the requirements be deleted or simplified for small entities, while still achieving comparable protection for the health of employees of small entities?

(d) What timetable would be appropriate to allow small entities sufficient time to comply?

29. The National Environmental Policy Act (NEPA) of 1969 (42 U.S.C. 4321 et seq.) requires that each Federal agency consider the environmental impact of major actions significantly affecting the quality of the human environment. Any person having information, data, or comments pertaining to possible environmental impacts is invited to submit them along with accompanying documentation to OSHA. Such impacts might include:

(a) Any positive or negative environmental effects that could result should a standard be adopted;

(b) Beneficial or adverse relationships between the human environment and productivity;

(c) Any irreversible commitments of natural resources which could be involved should a standard be implemented; and

(d) Estimates of the degree of reduction of BD and other hydrocarbons in the environment by the proposed OSHA standard and alternatives.

In particular, consideration should be given to the potential direct or indirect impacts of any action, or alternative actions, on water and air pollution, energy usage, solid waste disposal, or land use.

XIV. Public Participation—Notice of Hearing

Interested persons are invited to submit written data, views, and arguments with respect to this proposed standard. These comments must be postmarked on or before September 28, 1990, and submitted in quadruplicate to the Docket Officer, Docket No. H–041, Room N–2625, U.S. Department of Labor, Third Street and Constitution Avenue NW., Washington, DC 20210. Comments limited to 10 pages or less also may be transmitted by facsimile to (202) 523–5986 or (for FTS) 8–523–5986, provided the original and 3 copies are sent to the Docket Officer thereafter.

Written submissions must clearly identify the provisions of the proposal which are addressed and the position taken with respect to each issue. The data, views, and arguments that are submitted will be available for public inspection and copying at the above address. All timely written submissions will be made a part of the record of the proceeding.

Pursuant to section 6(b)(3) of the Act, an opportunity to submit oral testimony concerning the issues raised by the proposed standard including economic and environmental impacts, will be provided at two informal public hearings scheduled to begin at 10 a.m. on dates as follows: Washington, DC: December 11, 1990, in the Auditorium, Frances Perkins Building, U.S. Department of Labor, Third Street and Constitution Avenue, NW., Washington, DC 20210, and to begin at 10 a.m. on January 8, 1991 in New Orleans, Louisiana in the Le Pavillion Hotel (Denechaud Room) 833 Poydras Street, Telephone no. 504–581–3111.

A. Notice of Intention To Appear

All persons desiring to participate at the hearing must file in quadruplicate a Notice of Intention to Appear, postmarked on or before September 28, 1990, addressed to Mr. Tom Hall, OSHA Division of Consumer Affairs, Docket No. H–041, Room N–3649, U.S. Department of Labor, Third Street and Constitution Avenue, NW., Washington, DC 20210; telephone 202–523–8615. A Notice of Intention to Appear also may be transmitted by facsimile to 202–523–5986 or to 8–523–5986 (for FTS), provided the original and 3 copies of the Notice are sent to the above address thereafter.

The Notices of Intention to Appear, which will be available for inspection and copying at the OSHA Technical Data Center, Docket Office (Room N–2625), telephone 202–523–7894, must contain the following information:

(1) The name, address, and telephone number of each person to appear;

(2) The capacity in which the person will appear;

(3) The approximate amount of time requested for the presentation;

(4) The specific issues that will be addressed;

(5) A statement of the position that will be taken with respect to each issue addressed;

(6) Whether the party intends to submit documentary evidence, and if so, a brief summary of that evidence; and

(7) Which hearing the party wishes to testify.

B. Filing of Testimony and Evidence Before Hearing

Any party requesting more than 10 minutes for a presentation at the hearings, or who will submit documentary evidence, must provide in quadruplicate the complete text of his or her testimony, including any documentary evidence to be presented at the hearing, to the OSHA Division of Consumer Affairs. This material must be postmarked on or before October 19, 1990. The material will be available for inspection and copying at the Technical Data Center Docket Office. Each such submission will be reviewed in light of the amount of time requested in the Notice of Intention to Appear. In those instances where the information contained in the submission does not justify the amount of time requested, a more appropriate amount of time will be allocated and the participant will be notified of that fact.

Any party who has not substantially complied with this requirement may be limited to a 10 minute presentation, and may be requested to return for questioning at a later time. Any party who has not filed a Notice of Intention to Appear may be allowed to testify, as time permits, at the discretion of the Administrative Law Judge.

OSHA emphasizes that the hearing is open to the public, and that interested persons are welcome to attend. However, only persons who have filed proper Notices of Intention to Appear at the hearing will be entitled to ask questions and otherwise participate fully in the proceedings.

C. Conduct and Nature of Hearing

The Washington, DC and the New Orleans hearings will commence at 10 a.m. on December 11, and January 8, 1991 respectively. At that time any procedural matters relating to the hearing will be resolved.

The nature of the informal rulemaking hearings to be held is established in the legislative history of section 6 of the Act and is reflected by the OSHA hearing regulations (see 29 CFR 1911.15(a)). Although the presiding officer is an Administrative Law Judge and questioning by interested persons is allowed on crucial issues, it is clear that the proceedings shall remain informal and legislative in type. The essential intent is to provide an opportunity for effective oral presentation by interested persons which can be carried out expeditiously and in the absence of rigid procedures which might unduly impede or protract the rulemaking process.

The hearing will be conducted in accordance with 29 CFR part 1911. The hearing will be presided over by an Administrative Law Judge who will have all the powers necessary and appropriate to conduct a full and fair informal hearing as provided in 29 CFR part 1911 including the powers:

1. To regulate the course of the proceedings;

2. To dispose of procedural requests, objections and comparable matters;

3. To confine the presentation to the matters pertinent to the issues raised;

4. To regulate the conduct of those present at the hearing by appropriate means;

5. In the Judge's discretion, to question and permit the questioning of any witness and to limit the time for questioning; and

6. In the Judge's discretion, to keep the record open for a reasonable stated time to receive written information and additional data, views, and arguments from any person who has participated in oral proceedings.

D. Certification of Record and Final Determination After the Hearing

Following the close of the hearing and post-hearing comment period, the presiding Administrative Law Judge will certify the record to the Assistant Secretary of Labor for Occupational Safety and Health. The Administrative Law Judge does not make or recommend any decisions as to the content of the final standard.

The proposed standard will be reviewed in light of all oral and written submissions received as part of the record, and a permanent standard for occupational exposure to BD, will be issued, based upon the entire record in the proceeding including the written comments and data received from the public.

E. Authority

This document was prepared under the direction of Gerard F. Scannell, Assistant Secretary of Labor for Occupational Safety and Health, U.S. Department of Labor, 200 Constitution Avenue, NW., Washington DC 20210.

Pursuant to sections 4, 6(b), 8(c) and 8(g) of the Occupational Safety and Health Act of 1970 (29 U.S.C. 653, 655, 657), 29 CFR part 1911 and Secretary of Labor's Order Nos. 12–71 (36 FR 8754), 8–76 (41 FR 25059), 9–83 (48 FR 35736) or 1–90 (55 FR 9033) as applicable, it is hereby proposed to amend part 1910 of 29 CFR by adding new § 10.1051 as set forth below and deleting the reference to BD from table Z–1 of section 1910.1000. In addition, pursuant to section 4(b)(2) of the Act, OSHA has determined that this new standard would be more effective than the corresponding standards now in subpart B of part 1910, and in parts 1915, 1918, and 1926 of title 29, Code of Federal Regulations. Therefore, these corresponding standards would be superseded by this new § 1910.1051. This determination, and the application of the new standard to the maritime and construction industries, would be implemented by adding a new paragraph (1) to § 1910.19.

List of Subjects in 29 CFR Part 1910

1,3-Butadiene, Occupational safety and health, Chemicals, Cancer, Health Risk—assessment.

Signed at Washington, DC, this 17th day of July 1990

Gerard Scannell,

Assistant Secretary of Labor.

XV. Proposed Standard and Appendices

General Industry

Part 1910 of title 29 of the Code of Federal Regulations is proposed to be amended as follows:

PART 1910—[AMENDED]

Subpart B—[Amended]

1. The authority citation for subpart B of part 1910 is revised to read as follows:

Authority: Secs. 4, 6 and 8 of the Occupational Safety and Health Act, 29 U.S.C. 653, 655; 657; Walsh-Healey Act, 41 U.S.C. 35 *et seq.*,; Service Contract Act of 1965, 41 U.S.C. 351 et seq; sec. 107, Contract Work Hours and Safety Standards Act (Construction Safety Act), 40 U.S.C. 333; sec. 41, Longshoremen's and Harbor Workers' Compensation Act, 33 U.S.C. 941; National Foundation of Arts and Humanities Act, 20 U.S.C. 951 et seq.; Secretary of Labor's Order No. 12–71 (36 FR 8754); 8–76 (41 FR 25059); 9–83 (48 FR 35736) or 1–90 (55 FR 9033), as applicable, and 29 CFR part 1911.

Sections 1910.16 and 1910.19 also issued under 29 CFR part 1911.

2. By adding a new paragraph (1) to § 1910.19 to read as follows:

§ 1910.19 Special provisions for air contaminants.

* * * * *

(1) 1,3-Butadiene (BD): Section 1910.1051 shall apply to the exposure of every employee to BD in every employment and place of employment covered by §§ 1910.12, 1910.13, 1910.14, 1910.15, or 1910.16, in lieu of any different standard on exposure to BD which would otherwise be applicable by virtue of those sections.

Subpart Z—[Amended]

3. The authority citation for subpart Z of 29 CFR part 1910 is revised to read as follows:

Authority: Secs 4, 6 and 8, Occupational Safety and Health Act, 29 U.S.C. 653, 655, 657, Secretary of Labor's Orders Nos. 12–71 (36 FR 8754), 8–76 (41 FR 25059), 9–83 (48 FR 35736), or 1–90 (55 FR 9033), as applicable, and 29 CFR part 1911.

All of subpart Z issued under section 6(b) of the Occupational Safety and Health Act, 29 U.S.C. 655(b), except those substances listed in the Final Rule Limits column of Table Z–1–A, which have identical limits listed in the Transitional Limits columns of Table Z–1–A, Table Z–2 or Table Z–3. The latter were issued under section 6(a) (29 U.S.C. 655(a)).

Section 1910.1000, the Transitional Limits columns of Table Z–1–A, Table Z–2 and Z–3 also issued under 5 U.S.C. 553. Section 1910.1000, Tables Z–1–A, Z–2 and Z–3 not issued under 29 CFR part 1911 except for the arsenic, benzene, cotton dust and formaldehyde listings.

Section 1910.1001 also issued under section 107 of Contract Work Hours and Safety Standards Act, 40 U.S.C. 333.

Section 1910.1002 not issued under 29 U.S.C. 655 or 29 CFR part 1911; also issued under 5 U.S.C. 553.

Section 1910.1003 through 1910.1018 also issued under 29 U.S.C. 653.

Section 1910.1025 also issued under 29 U.S.C. 653 and 5 U.S.C. 553.

Section 1910.1028 also issued under 29 U.S.C. 653.

Section 1910.1043 also issued under 5 U.S.C. 551 et. seq.Section 1910.1045 and 1910.1047 also issued under 29 U.S.C. 653.

Section 1910.1048 also issued under 29 U.S.C. 653.

Section 1910.1051 also issued under. 29 U.S.C. 653.

Section 1910.1200, 1910.1499 and 1910.1500 also issued under 5 U.S.C. 553.

§ 1910.1000 [Amended]

4. By deleting the entry "Butadiene (1,3-Butadiene) 1–000 ppm, 2000 mg/m^3" from table Z–1–A of § 1910.1000.

5. By adding a new § 1910.1051 to read as follows:

§ 1910.1051 1,3-Butadiene.

(a) *Scope and application.* (1) This section applies to all occupational exposures to 1,3-Butadiene (BD), Chemical Abstracts Service Registry No. 106–99–0 except as provided in paragraph (a)(2) of this section.

(2) This section does not apply to the processing, use, or handling of products containing BD where objective data are reasonably relied upon that demonstrate that the product is not capable of releasing BD in airborne concentrations at or above the action level or in excess of the STEL under the expected conditions of processing, use, or handling that will cause the greatest possible release.

(3) Where products containing BD are exempted under paragraph (a)(2) of this section, the employer shall maintain records of the objective data supporting that exemption and the basis for the employer's reliance on the data, as provided in paragraph (k)(1) of this section.

(b) *Definitions:* For the purpose of this section, the following definitions shall apply:

Action level means a concentration of airborne BD of 1.0 ppm calculated as an eight (8)-hour time-weighted average.

Assistant Secretary means the Assistant Secretary of Labor for Occupational Safety and Health, U.S. Department of Labor, or designee.

Authorized person means any person specifically authorized by the employer whose duties require the person to enter a regulated area, or any person entering such an area as a designated representative of employees for the purpose of exercising the right to observe monitoring and measuring procedures under paragraph (1) of this section, or any other person authorized by the Act or regulations issued under the Act.

1,3-Butadiene means an organic compound with chemical formula $CH_2=CH-CH=CH_2$. The chemical "1,3-butadiene" (Chemical Abstracts Registry Number 106–99–0) is a colorless, noncorrosive, flammable gas with a mild aromatic odor at standard ambient temperature and pressure. It has a molecular weight of 54.1, a boiling point of −4.7°C at 760 mm Hg, a lower explosive limit of 2%, and an upper explosive limit of 11.5%. Its vapor is almost twice that of air. It is slightly soluble in water, somewhat soluble in methanol and ethanol, and readily soluble in less polar organic solvents such as hexane, benzene, and toluene. It is highly reactive, dimerizes to 4-vinylcyclohexene, and polymerizes easily. Because of its low odor threshold, high flammability and explosiveness, BD has been handled with extreme care in the industry.

Day means any part of a calendar day.

Director means the Director of the National Institute for Occupational Safety and Health, U.S. Department of Health and Human Services, or designee.

Emergency means any occurrence such as, but not limited to, equipment failure, rupture of containers, or failure of control equipment that may or does result in an unexpected significant release of BD.

Employee exposure means exposure to airborne BD which would occur if the employee were not using respiratory protective equipment.

Regulated area means any area where airborne concentrations of BD exceed or can reasonably be expected to exceed the permissible exposure limits, either the 8-hour time weighted average exposure of 2 ppm or the short-term exposure limit of 10 ppm for 15 minutes.

(c) *Permissible exposure limits (PELs)*—(1) *Time-weighted average (TWA) limit.* The employer shall ensure that no employee is exposed to an airborne concentration of BD in excess of two (2) parts BD per million parts of air (2 ppm) as an eight (8)-hour time-weighted average (8-hour TWA).

(2) *Short-term exposure limit (STEL).* The employer shall ensure that no employee is exposed to an airborne concentration of BD in excess of ten parts of BD per million parts of air (10 ppm) as determined over a sampling period of fifteen (15) minutes.

(d) *Exposure monitoring*—(1) *General.* (i) Determinations of employee exposure shall be made from breathing zone air samples that are representative of the 8 hour TWA and 15 minute short-term exposure of each employee.

(ii) Representative 8-hour TWA employee exposure shall be determined on the basis of one or more samples representing full-shift exposure for each shift for each job classification in each work area.

(iii) Representative 15 minutes short-term employee exposures shall be determined on the basis of one or more samples representing 15 minutes exposures associated with operations that are most likely to produce exposures above the STEL for each shift for each job classification in each work area.

(iv) Except for initial monitoring as required under paragraph (d)(2) of this section, where the employer can document that exposure levels are equivalent for similar operations in different work shifts, the employer need only determine representative employee exposure for that operation during one shift on which the highest exposure is expected.

(2) *Initial monitoring.* (i) Each employer who has a workplace or work operation covered by this standard, except as provided for in paragraph (a)(2) of this section, shall perform initial monitoring to determine accurately the airborne concentrations of BD to which employees may be exposed.

(ii) The initial monitoring required under paragraph (d)(2)(i) of this section shall be completed within 60 days of the effective date of this standard or the introduction of BD into the workplace.

(iii) Where the employer has monitored within one year prior to the effective date of this standard and the monitoring satisfies all other requirements of this section, the employer may rely on such earlier monitoring results to satisfy the requirements of paragraph (d)(2)(i) of this section, provided that the conditions under which the initial monitoring was conducted remain unchanged.

(3) *Periodic Monitoring and its frequency.* (i) If the monitoring required by paragraph (d)(2) of this section reveals employee exposure at or above the action level but at or below both the 8-hour TWA limit and the 15-minute STEL, the employer shall repeat such monitoring for each such employee at least every six months.

(ii) If the monitoring required by paragraph (d)(2)(i) of this section reveals employee exposure above the 8-hour TWA limit, the employer shall repeat such monitoring for each such employee at least every three months.

(iii) If the monitoring required by paragraph (d)(2) of this section reveals employee exposure above the 15-minute STEL, the employer shall repeat such monitoring for each such individual at least every three months to evaluate exposures to employees subject to short term exposures.

(iv) The employer may alter the monitoring schedule from every three months to every six months for any employee for whom two consecutive measurements taken at least 7 days apart indicate that the employee's exposure has decreased to or below the 8-hour TWA, but is at or above the action level.

(4) *Termination of monitoring.* (i) If the initial monitoring required by paragraph (d)(2) of this section reveals employee exposure to be below the action level and at or below the 15-minute STEL, the employer may discontinue the monitoring for those employees whose exposures are represented by the initial monitoring except as otherwise required by paragraph (d)(5) of this section. If the periodic monitoring required by paragraph (d)(3) of this section reveals that employee exposures, as indicated by at least two consecutive measurements taken at least 7 days apart, are below the action level and at or below that STEL, the employer may dicontinue the monitoring for those employees who are represented by such monitoring except as otherwise required by paragraph (d)(5) of this section.

(5) *Additional monitoring.* (i) The employer shall institute the exposure monitoring required under paragraphs (d)(2) and (d)(3) of this section whenever there has been a change in the production, process, control equipment, personnel or work practices that may result in new or additional exposures to BD or when the employer has any reason to suspect that a change may result in new or additional exposures.

(ii) Whenever spills, leaks, ruptures or other breakdowns occur that may lead to employee exposure above the action

level or above the STEL, the employer shall repeat the monitoring which is required by paragraph (d)(2)(i) of this section after the clean up of the spill or repair of the leak, rupture or other breakdown.

(6) *Accuracy of monitoring.* Monitoring shall be accurate, to a confidence level of 95 percent, to within plus or minus 25 percent for airborne concentrations of BD at or above the 2 ppm TWA limit and to within plus or minus 35 percent for airborne concentrations of BD at or above the action level of 1.0 ppm and below the 2 ppm TWA limit.

(7) *Employee notification of monitoring results.* (i) The employer shall, whithin 15 working days after the receipt of the results of any monitoring performed under this standard, notify the affected employee of these results in writing either individually or by posting of results in an appropriate location that is accessible to affected employees.

(ii) The written notification required by paragraph (d)(7)(i) of this section shall contain the corrective action being taken by the employer to reduce employee exposure to or below the 8 hour TWA limit or STEL, wherever monitoring results indicated that the 8-hour TWA or the 15-minute STEL has been exceeded.

(e) *Regulated areas.* (1) The employer shall establish a regulated area wherever occupational exposures to airborne concentrations of BD may exceed the permissible exposure limits, either the 8-hour TWA of 2 ppm or 15-minute STEL of 10 ppm.

(2) Access to regulated areas shall be limited to authorized persons.

(3) Regulated areas shall be demarcated from the rest of the workplace in any manner that minimizes the number of employees exposed to BD within the regulated area.

(4) An employer at a multiemployer worksite who establishes a regulated area shall communicate the access restrictions and locations of these areas to other employers with work operations at that worksite.

(f) *Methods of compliance*—(1) *Engineering controls and work practices.* (i) The employer shall institute engineering controls and work practices to reduce and maintain employee exposure to or below the permissible exposure limits, except to the extent that the employer can establish that these controls are not feasible or where paragraph (g)(1) of this section applies.

(ii) Wherever the feasible engineering controls and work practices which can be instituted are not sufficient to reduce employee exposure to or below the PEL the employer shall use them to reduce employee exposure to the lowest levels achievable by these controls and shall supplement them by the use of respiratory protection that complies with the requirements of paragraph (g) of this section.

(2) *Compliance program.* (i) Where any exposures are over the PELs the employer shall establish and implement a written program to reduce employee exposure to or below the PELs primarily by means of engineering and work practice controls, as required by paragraph (f)(1) of this section, and by the use of respiratory protection where required or permitted under this section. No compliance plan is required if all exposures are under the PELs.

(ii) The written compliance program shall include a schedule for development and implementation of the engineering controls and work practice controls including periodic leak detection surveys and a written plan for emergency situations, as specified in paragraph (h)(1)(i) of this section.

(iii) Written plans for a program required in paragraph (f)(2) of this section shall be furnished upon request for examination and copying to the Assistant Secretary, the Director, affected employees and designated employee representatives. Such plans shall be reviewed at least every 12 months, and shall be updated as necessary to reflect significant changes in the status of the employer's compliance program.

(iv) The employer shall not implement a schedule of employee rotation as a means of compliance with the PELs.

(g) *Respiratory protection and personal protective equipment*—(1) *General.* The employer shall provide respirators, and ensure that they are used, where required by this section. Respirators shall be used in the following circumstances.

(i) During the time interval necessary to install or implement feasible engineering and work practice controls;

(ii) In work operations, such as maintenance and repair activities, vessel cleaning, or other activities for which engineering and work practice controls are demonstrated to be infeasible, and exposures are intermittent in nature and limited in duration;

(iii) In work situations where feasible engineering and work practice controls are not yet sufficient to reduce exposure to or below the PELs; and

(iv) In emergencies.

(2) *Respirator selection.* (i) Where respirators are required or allowed under this section, the employer shall select and provide, at no cost to the employee, the appropriate respirator as specified in Table 1, and shall ensure that the employee uses the respirator provided.

TABLE 1—MINIMUM REQUIREMENTS FOR RESPIRATORY PROTECTION FOR AIRBORNE BD

Concentration of Airborne BD (ppm) or condition of use	Minimum required respirator
If less than or equal to 50 PPM.	(a) Full facepiece air-purifying respirator equipped with organic vapor or BD approved canister, front or-back-mounted (industrial sized). (b) Hood or helmet powered air-purifying respirator equipped with organic vapor or BD approved canister. (c) Continuous-flow supplied air respirator equipped with hood or helmet.
If concentration exceeds 50 PPM.	(a) Full facepiece powered air purifying respirator equipped with Organic Vapor or BD approved canister. (b) Full facepiece self-contained breathing apparatus operated in negative pressure (demand) mode. (c) Full facepiece supplied-air respirator operated in pressure demand or other positive pressure mode. (d) Full facepiece self-contained breathing apparatus operated in pressure demand or other positive pressure mode. (e) Full facepiece pressure demand (a) or other supplied-air respirator with auxiliary self-contained air supply.
Firefighting, or unknown concentration (such as in emergencies).	(a) Full facepiece self-contained breathing apparatus operated in pressure demand or other positive pressure mode.
Escape	(a) Any respirator described above.

NOTE: Respirators approved for use in higher concentrations are permitted to be used in lower concentrations.

(ii) The employer shall select respirators from among those jointly approved by the Mine Safety and Health Administration (MSHA) or by the National Institute for Occupational Safety and Health (NIOSH) under the provisions of 30 CFR Part 11. Negative pressure respirators shall have filter

element, approved by MSHA/NIOSH for organic vapors or BD.

(iii) Any employee who cannot wear a negative pressure respirator shall be given the option of wearing a respirator with less breathing resistance such as a powered air-purifying respirator or supplied air respirator.

(3) *Respirator program.* Where respiratory protection is required by this section, the employer shall institute a respirator program in accordance with 29 CFR 1910.134(b), (d), (e), and (f).

(4). *Respirator use.* (i) Where air-purifying respirators are used, the employer shall replace the air purifying element at 90% the expiration of service life or at the beginning of each shift in which they will be used, whichever comes first. The employer shall assure that each filter element is dated at the beginning of use.

(ii) If an air purifying element becomes available with a clearly visible end of useful life indicator for BD approved by MSHA/NIOSH, the element may be used until such time as the indicator shows no further useful life.

(iii) Organic vapor canisters for BD shall have a minimum service life of four hours when tested under the maximum concentration expected in the work environment.

(iv) The employer shall permit employees who wear respirators to leave the regulated area to wash their faces and respirator facepieces as necessary in order to prevent skin irritation associated with respirator use or to change the filter elements of air-purifying respirators whenever they detect a change in breathing resistance or chemical vapor breakthrough.

(5) *Respirator fit testing.* (i) The employer shall perform either qualitative or quantitative fit testing as required under 29 CFR 1910.134 for employees who must wear tight fitting negative or positive pressure respirators. The test shall be used to select a respirator facepiece which exhibits minimum leakage and provides the required protection as prescribed in Table 35. The employer shall provide and assure that the employee wears a respirator demonstrated by the fit test to provide the required protection.

(ii) The employer shall follow the test protocols outlined in appendix E of this standard for whichever type of fit testing the employer chooses.

(6) *Protective Clothing and Equipment.* Personal protective clothing and equipment shall be worn where appropriate to prevent eye contact and limit dermal exposure to liquified BD and solutions containing BD. Protective clothing and equipment shall be provided by the employer at no cost to the employee and the employer shall assure its use where appropriate. Eye and face protection shall meet the requirements of 29 CFR 1910.133.

(h) *Emergency situations*—(1) *Written plan.* (i) A written plan for emergency situations shall be developed, or an existing plan shall be modified to contain the elements specified in 29 CFR 1910.38, "Employee emergency plans and fire prevention plans," for each workplace where there is a possibility of an emergency. Appropriate portions of the plan shall be implemented in the event of an emergency.

(ii) The plan shall specifically provide that employees engaged in correcting emergency conditions shall be equipped with respiratory protection as required by paragraph (g) of this section until the emergency is abated.

(2) *Alerting employees.* Where there is the possibility of employee exposure to BD due to an emergency, means shall be developed to alert potentially affected employees of such occurrences promptly. Affected employees shall be immediately evacuated from the area in the event that an emergency occurs.

(i) *Medical surveillance*—(1) *Employees covered.* (i) The employer shall institute medical surveillance programs for employees exposed to BD at concentrations at or above the action level (AL) for at least 30 days a year or for employees who are or may be exposed to BD at or above the PEL or STEL for at least 10 days a year.

(ii) The employer shall make available a medical evaluation of the cardiopulmonary function for all employees whose exposures require them to use respirators regardless of the duration of exposure.

(iii) The employer shall make medical surveillance available for all employees exposed to BD in an emergency.

(2) *Examination by a physician.* (i) All medical procedures shall be performed by or under the supervision of a licensed physician and all laboratory tests are to be conducted by an accredited laboratory. All examinations and procedures shall be provided without cost to the employee, without loss of pay, and at a reasonable time and place. Persons other than licensed physicians who administer pulmonary function tests required by this standard shall complete a training course in spirometry sponsored by an appropriate governmental, academic, or professional institution.

(ii) For any employee required to use a respirator, the examining physician shall certify his or her ability to use a respirator.

(3) *Frequency of examinations.* The employer shall make available medical examinations and consultations to each employee covered under paragraph (i)(1) of this standard on the following schedules:

(i) Within 60 days of the effective date of this standard, or before the time of initial assignment of the employee.

(ii) Annually.

(iii) At termination of employment or reassignment to an area where exposure to BD is consistently below the action level, if three months or more have elapsed since last annual medical examination.

(iv) Immediately after every emergency.

(4) *Content.* Medical examinations made available pursuant to paragraphs (i)(1) of this standard shall include:

(i) A detailed occupational and medical history with particular emphasis on:

(A) Medicine taken or exposure to other chemicals that adversely affect the hematopoietic or reticuloendothelial systems;

(B) Any reproductive difficulties;

(C) Any other information determined by the examining physician to be necessary.

(ii) A thorough physical examination. For workers required to wear respirators, the physician shall direct special attention to the cardiopulmonary system.

(iii) A complete blood count including platelet count.

(iv) Any other appropriate test which the examining physician deems necessary by sound medical practice.

(5) *Additional examinations and referrals.* (i) Where the results of the medical examination indicate abnormalities of the hematopoietic or reticuloendothelial systems for which no non-occupational cause is known, the examining physician shall refer the employee to an appropriate specialist for further evaluation and the employer shall assure that these tests are provided.

(ii) Following an emergency exposure, medical surveillance shall be made available pursuant to paragraph (i)(1)(iii) and (i) (3)(iv) of this section and shall include a complete blood count following the exposure and at three months, six months, and twelve months thereafter.

(iii) The content of the medical examinations or consultations made available pursuant to paragraph (i)(4) of this standard shall be determined by the examining physician and shall include evaluation of fertility and other tests, if

requested by the employee and deemed appropriate by the physician.

(6) *Information provided to the physician.* The employer shall provide the following information to the examining physician and to any specialist involved in the diagnosis:

(i) A copy of this regulation including its appendices;

(ii) A description of the affected employee's duties as they relate to the employee's exposure;

(iii) The employee's actual or representative exposure level during his employment tenure including frequency of abnormal events (emergencies);

(iv) A description of any personal protective equipment used or to be used; and

(v) Information from previous employment-related medical examinations of the affected employee which is not otherwise available to the examining physician or the specialist.

(7) *Physician's written opinion.* (i) For each examination required by this standard, the employer shall obtain and provide the employee with a copy of the examining physician's written opinion within 15 days of the examination. The written opinion shall be limited to the following information:

(A) The occupationally pertinent results of the medical examination and tests;

(B) The physician's opinion concerning whether the employee has any detected medical conditions which would place the employee's health at greater than normal risk of material impairment from exposure to BD. Clinical and any other test results shall be used by the physician to support his/her findings and recommendations;

(C) The physician's recommended limitations upon the employee's exposure to BD or upon the employee's use of protective clothing or equipment and respirators; and

(D) A statement that the employee has been informed by the physician of the results of the medical examination and any medical conditions resulting from BD exposure which require further explanation or treatment.

(ii) The written opinion obtained by the employer shall not reveal specific records, findings, and diagnoses that have no bearing on the employee's ability to work with BD or other regulated substances.

(j) *Communication of 1,3-Butadiene hazards to employees*—(1) *Warning Signs.* (i) Warning signs shall be provided and displayed in regulated areas. In addition, warning signs shall be posted at all approaches to regulated areas so that an employee may read the signs and take necessary protective steps before entering the area.

(ii) The warning signs required by paragraph (j)(1)(i) of this section shall bear the following information.

DANGER. 1,3-BUTADIENE. POTENTIAL CANCER AND REPRODUCTIVE HAZARD. CAN CAUSE LUNG AND KIDNEY DAMAGE. AUTHORIZED PERSONNEL ONLY. RESPIRATORS AND PROTECTIVE CLOTHING REQUIRED IN THIS AREA

(2) *Warning Labels.* (i) Shipping and storage containers containing BD, shall bear appropriate warning labels, as specified in paragraph (j)(2)(ii) of this section.

(ii) The labels shall comply with the requirements of the Hazard Communication Standard 29 CFR 1910.1200(f) (general industry) and 29 CFR 1926.59 (construction industry), and shall include the following information:

DANGER. CONTAINS 1,3-BUTADIENE. POTENTIAL CANCER AND REPRODUCTIVE HAZARD

(3) *Material safety data sheets.* Employers who are manufacturers or importers of BD shall comply with the requirements regarding development and distribution of material safety data sheets as specified in 29 CFR 1910.1200(f) of OSHA's Hazard Communication Standard. All employers with employees potentially exposed to BD shall maintain material safety data sheets and provide their employees with access to them, in accordance with the requirements of 29 CFR 1910.1200(g) and 29 CFR 1926.59(g).

(4) *Employee information and training.* Employers shall provide employees with information and training in accordance with the requirements of the Hazard Communication Standard, 29 CFR 1910.1200(h) (general industry), and 29 CFR 1926.59(h) (construction industry). In addition:

(i) The employer shall institute a training program for all employees who are potentially exposed to BD at or above the action level or the STEL, assure employee participation in the program and maintain a record of the contents of such program.

(ii) Training shall be provided prior to or at the time of initial assignment to a job potentially involving exposure to BD and at least annually thereafter.

(iii) The training program shall be conducted in a manner that the employee is able to understand. The employer shall assure that each employee is informed of the following:

(A) The health hazards associated with BD exposure, with special attention to the information incorporated in Appendix A;

(B) The quantity, location, manner of use, release, and storage of BD and the specific nature of operations that could result in exposure to BD, especially exposures above the PEL or STEL;

(C) The engineering controls and work practices associated with the employee's job assignment;

(D) The measures employees can take to protect themselves from exposure to BD, including a review of their habits, such as smoking and personal hygiene; and specific procedures the employer has implemented to protect employees from exposure to BD, such as appropriate work practices, emergency procedures, and personal protective equipment;

(E) The details of the hazard communication program developed by the employer, including an explanation of the signs, labeling system and material safety data sheets, and how employees can obtain and use the appropriate hazard information;

(F) The purpose, proper selection, fitting, proper use, and limitations of respirators and protective clothing;

(G) The purpose and a description of the medical surveillance program required by paragraph (i) of this section;

(H) The contents of this standard and its appendices; and

(I) The right of any employee exposed to BD at or above the action level or above the STEL to obtain:

(*1*) medical examinations as required by paragraph (1) at no cost to the employee;

(*2*) the employee's medical records required to be maintained by paragraph (k)(3) of this section; and

(*3*) all air monitoring results representing the employee's exposure to BD and required to be kept by paragraph (k)(2) of this section.

(iv) Access to information and training materials.

(A) The employer shall make a copy of this standard and its appendices readily available without cost to all affected employees and shall provide a copy if requested.

(B) The employer shall provide to the Assistant Secretary or the Director, upon request, all materials relating to the employee information and the training program.

(k) *Recordkeeping*—(1) *Objective data for exempted operations.* (1) Where the processing, use, or handling of products made from or containing BD are exempted from other requirements of this section under paragraph (a)(2) of this section, or where objective data have been relied on in lieu of initial monitoring under paragraph (d)(2)(ii) of this section, the employer shall establish

and maintain an accurate record of objective data reasonably relied upon in support of the exemption.

(ii) This record shall include at least the following information:

(A) The product qualifying for exemption;

(B) The source of the objective data;

(C) The testing protocol, results of testing, and/or analysis of the material for the release of BD;

(D) A description of the operation exempted and how the data support the exemption; and

(E) Other data relevant to the operations, materials, processing, or employee exposures covered by the exemption.

(iii) The employer shall maintain this record for the duration of the employer's reliance upon such objective data.

(2) *Exposure measurements.* (i) The employer shall keep an accurate record of all measurements taken to monitor employee exposure to BD as prescribed in paragraph (d) of this section.

(ii) The record shall include at least the following information:

(A) The date of measurement;

(B) The operation involving exposure to BD which is being monitored;

(C) Sampling and analytical methods used and evidence of their accuracy;

(D) Number, duration, and results of samples taken;

(E) Type of protective devices worn, if any; and

(F) Name, social security number and exposure of the employees whose exposures are represented.

(iii) The employer shall maintain this record for at least thirty (30) years, in accordance with 29 CFR 1910.20.

(3) *Medical surveillance.* (i) The employer shall establish and maintain an accurate record for each employee subject to medical surveillance by paragraph (i)(1)(i) of this section, in accordance with 29 CFR 1910.20.

(ii) The record shall include at least the following information:

(A) The name and social security number of the employee;

(B) Physicians' written opinions;

(C) Any employee medical complaints related to exposure to BD; and

(D) A copy of the information provided to the physician as required by paragraphs (i)(6) (ii) through (v) of this section.

(iii) The employer shall ensure that this record is maintained for the duration of employment plus thirty (30) years, in accordance with 29 CFR 1910.20.

(4) *Availability.* (i) The employer, upon written request, shall make all records required to be maintained by this section available for examination and copying to the Assistant Secretary and the Director.

(ii) The employer, upon request, shall make an exemption and exposure records required by paragraphs (k)(1) and (k)(2) of this section available for examination and copying to affected employees, former employees, designated representatives and the Assistant Secretary, in accordance with 29 CFR 1910.20(a)–(e) and (g)–(i).

(iii) The employer, upon request, shall make employee medical records required by paragraph (k)(3) of this section available for examination and copying to the subject employee, anyone having the specific written consent of the subject employee, and the Assistant Secretary, in accordance with 29 CFR 1910.20.

(5) *Transfer of records.* (i) The employer shall comply with the requirements concerning transfer of records set forth in 29 CFR 1910.20(h).

(ii) Whenever the employer ceases to do business and there is no successor employer to receive and retain the records for the prescribed period, the employer shall notify the Director at least 90 days prior to disposal and transmit them to the Director.

(l) *Observation of monitoring*—(1) *Employee observation.* The employer shall provide affected employees or their designated representatives an opportunity to observe any monitoring of employee exposure to BD conducted in accordance with paragraph (d) of this section.

(2) *Observation procedures.* When observation of the monitoring of employee exposure to BD requires entry into an area where the use of protective clothing or equipment is required, the observer shall be provided with and be required to use such clothing and equipment and shall comply with all other applicable safety and health procedures.

(m) *Dates*—(1) *Effective date.* This section shall become effective sixty (60) days after the date of publishing the final standard in the Federal Register.

(2) *Start-up dates.* (i) The requirements of paragraphs (c) through (l) of this section, including feasible work practice controls but not including engineering controls specified in paragraph (f)(1), shall be complied with within one-hundred and eighty (180) days after the effective date of this section.

(ii) Engineering controls specified by paragraph (f)(1) of this section shall be implemented within one (1) year after the effective date of this section.

(n) *Appendices.* The information contained in the appendices is not intended, by itself to, create any additional obligations not otherwise imposed or to detract from any existing obligation. The protocols on respiratory fit testing in Appendix E are mandatory.

Appendix A to § 1910.1051: Substance Safety Data Sheet for 1.3-Butadiene

I. Substance Identification

A. Substance: 1.3-Butadiene ($CH_2=Ch-CH=CH_2$).

B. Synonyms: 1,3-Butadiene; butadiene; biethylene; bi-vinyl; divinyl; butadiene-1,3; buta-1,3-dine; erythrene; NCI–C50602; CAS–106–99–0.

C. BD can be found as a gas or liquid.

D. BD is used in production of styrene-butadiene rubber and polybutadiene rubber for the tire industry. Other uses include copolymer latexes for carpet backing and paper coating, as well as resins and polymers for pipes and automobile and appliance parts. It is also used as an intermediate in the production of such chemicals as fungicides.

E. Appearance and odor: BD is a colorless, non-corrosive, flammable gas at standard ambient temperature and pressure with a mild aromatic odor.

F. Permissible exposure: Exposure may not exceed 2 part BD per million parts of air average over the 8-hour work day, nor may short-term exposure exceed 10 parts of BD per million parts of air averaged over a 15-minute period.

II. Health Hazard Data

A. BD can affect the body if it is inhaled or if the liquid comes in contact with the eyes or skin.

B. Effect of overexposure: Overexposure to BD may cause irritation of the eye, nose, and throat. It may also cause drowsiness and lightheadness. Exposure to very high concentrations may cause unconsciousness and death. Spilled on the skin, it may cause frostbite and irritation.

C. Long-term (chronic) exposure: BD has been shown to cause cancer in two animal studies. BD was found to be a weak carcinogen for Sprague-Dawley rats and to be a potent carcinogen-neoplastic lesions at multiple target sites in B63F1 mice. Among six epidemiologic studies, four studies reported increases in mortality from cancer of lymphopoietic system and these studies reported increases in mortality from leukemia. Two studies indicated significantly elevated mortality from stomach neoplasms.

D. Reporting signs and symptoms: You should inform your employer if you develop any signs or symptoms and suspect that they are caused by exposure to BD.

III. Emergency First Aid Procedures

In the event of emergency, institute first aid procedures and send for first aid or medical assistance.

A. Eye and Skin Exposures: If there is a potential that pressurized liquid BD can come in contact with eye or skin, face shields and skin protective equipment must be provided and used. If liquid BD comes in contact with eye, get medical attention. Contact lenses should not be worn when working with this chemical.

B. Breathing: If a person breathes in large amounts of BD, move the exposed person to fresh air at once. If breathing has stopped, perform artificial respiration. Keep the affected person warm and at rest. Get medical attention as soon as possible.

C. Rescue: Move the affected person from the hazardous exposure. If the exposed person has been overcome, notify someone else and put into effect the established emergency rescue procedures. Do not become a casualty. Understand the facility's emergency rescue procedures and know the locations of rescue equipment before the need arises.

IV. Respirators and Protective Clothing

A. *Respirators.* Good industrial hygiene practices recommend that engineering controls be used to reduce environmental concentrations to the permissible exposure level. However, there are some exceptions where respirators may be used to control exposure. Respirators may be used when engineering and work practice controls are not technically feasible, when such controls are in the process of being installed, or when these controls fail and need to be supplemental. Respirators may also be used for operations which require entry into tanks or closed vessels, and in emergency situations. If the use of respirators is necessary, the only respirators permitted are those that have been approved by the Mine Safety and Health Administration (OSHA) or the National Institute for Occupational Safety and Health (NIOSH). In addition to respirator selections, a complete respiratory protection program should be instituted which includes regular training, maintenance, inspection, cleaning, and evaluation. If you can smell BD while wearing a respirator, proceed immediately to fresh air. If you experience difficulty in breathing while wearing a respirator, tell your employer.

B. *Protective Clothing.* Employees should be provided with and required to use impervious clothing, gloves, face shields (eight-inch minimum), and other appropriate protective clothing necessary to prevent the skin from becoming frozen by contacting with liquid BD or by contacting with vessel containing liquid BD. Any clothing which becomes wet with liquid BD should be removed immediately and not reworn until the BD has evaporated.

Employees should be provided with and required to use splash-proof safety goggles where liquid BD may contact the eyes.

V. Precautions for Safe Use, Handling, and Storage.

A. *Fire and Explosion Hazards.* BD is a flammable gas and can easily form explosive mixtures in air. It has a lower explosive limit of 2%, and an upper explosive limit of 11.5%. It has an ignition temperature of 804–F. It is heavier than air (vapor density, 1.9) and may travel a considerable distance to a source of ignition and flash back. Usually it contains inhibitors to prevent self-polymerization (which is accompanied by evolution or heat) and to prevent formation of peroxides. At elevated temperatures, such as in fire conditions, polymerization may take place. If the polymerization takes place in a container, there is a possibility of violent rupture of the container.

B. *Life Hazard.* Slightly toxic but may cause asphyxiation by exclusion of oxygen. Slight respiratory irritant. Direct expansion on skin may cause freeze burns.

C. *Storage.* Protect against physical damage. Outside or detached storage is preferred. Inside storage should be in a cool, well-ventilated, noncombustible location, away from all possible sources of ignition. Store cylinders vertically and do not stack. Do not store with oxidizing material.

D. *Usual Shipping Containers.* Liquefied in steel pressure apparatus.

E. *Electrical Equipment.* Electrical installations in Class I hazardous locations, as defined in Article 500 of the National Electrical Code, should be in accordance with Article 501 of the Code. If explosion-proof electrical equipment is necessary, it shall be suitable for use in Group B. Group D equipment may be used if such equipment is isolated in accordance with Section 501–5(a) by sealing all conduit 1/2 inch size or larger. See Explosion Venting Guide (NFPA No. 68), National Electrical Code (NFPA No. 70), State Electricity (NFPA No. 77), Lightning Protection Code (NFPA No. 78), Fire-Hazard Properties of Flammable Liquids, Gases and Volatile Solids (NFPA No. 325M), and Chemical Safety Data Sheet SD–55 (Manufacturing Chemists' Association, Inc.).

F. *Fire Fighting.* Stop flow of gas. Use water to keep fire-exposed containers cool. BD vapors are uninhibited and may from polymers in vents or flame arrester of storage tanks, resulting in stopping of vents. Fire extinguishers and quick drenching facilities must be readily available, and you should know where they are and how to operate them.

G. *Spill and Leak.* Persons not wearing protective equipment and clothing should be restricted from areas of spills or leaks until cleanup has been completed. If BD is spilled or leaked, the following steps should be taken:

1. Remove all ignition sources.
2. Ventilate area of spill or leak.
3. If in liquid form, for small quantities, absorb on paper towels. Evaporate in a safe place (such as a fume hood). Allow sufficient time for evaporating vapors to completely clear the hood ductwork. Burn the paper in a suitable location away from combustible materials. Large quantities can be collected and atomized in a suitable combustion chamber.
4. If in gaseous form, stop flow of gas. If source of leak is a cylinder and the leak cannot be stopped in place, remove the leaking cylinder to a safe place in the open air and repair the leak or allow the cylinder to empty.

H. Methods of Waste Disposable.

1. If in liquid form, by atomizing in a suitable combustion chamber.
2. If in gaseous form, by burning in a safe location or in a suitable combustion chamber.

I. You must not keep food, beverage, or smoking materials, nor are you permitted to eat or smoke in regulated areas where BD concentrations are above the permissible exposure limits.

J. Ask your supervisor where BD is used in your work area and for any additional plant safety and health rules.

VI. Medical Requirements.

Your employer is required to offer you the opportunity to participate in a medical surveillance program if you are exposed to BD at concentrations exceeding the action level for more than 30 days a year or at concentrations exceeding the PELs for more than 10 days a year. If you are exposed to BD at concentrations over either of the PELs for more than 10 days a year, the medical surveillance will also include tests to ensure that you are able to wear the respirator that you are assigned. Your employer must provide all medical examinations relating to your BD exposure at a reasonable time and place and at no cost to you.

VII. Observation of Monitoring

Your employer is required to perform measurements that are representative of your exposure to BD and you or your designated representative are entitled to observe the monitoring procedure. You are entitled to observe the steps taken in the measurement procedure, and to record the results obtained. When the monitoring procedure is taking place in an area where respirators or personal protective clothing and equipment are required to be worn, you or your representative must also be provided with, and must wear protective clothing and equipment.

VIII. Access To Information

A. Each year, your employer is required to inform you of the information contained in this appendix. In addition, your employer must instruct you in the proper work practices for using BD, emergency procedures, and the correct use of protective equipment.

B. Your employer is required to determine whether you are being exposed to BD. You or your representative has the right to observe employee measurements and to record the results obtained. Your employer is required to inform you of your exposure. If your employer determines that you are being overexposed, he or she is required to inform you of the actions which are being taken to reduce your exposure to within permissible exposure limits.

C. Your employer is required to keep records of your exposures and medical examinations. These records must be kept by the employer for at least thirty (30) years.

D. Your employer is required to release your exposure and medical records to you or your representative upon your request.

Appendix B to § 1910.1051: Substance Technical Guidelines for 1,3-Butadiene

I. Physical and Chemical Data

A. Substance identification:

1. Synonyms: 1,3-Butadiene; butadiene; biethylene; bivinyl; divinyl; butadiene-1,3; buta-1,3 diene; erythrene; NCI–C50620; CAS–106–99–0
2. Formula: CH_2–CH–CH–CH_2
3. Molecular weight: 54.1

B. Physical data:

1. Boiling point (760 mm Hg.): −4.7 °C (23.5 °F).
2. Specific gravity (water=1): 0.62
3. Vapor density (air=1 at boiling points): 1.87
4. Vapor pressure at 20 °C (68 °F): 910 mm Hg
5. Solubility in water, g/100 g water at 20 °C (68 °F):0.05.
6. Appearance and odor: colorless gas above boiling point with a mildly aromatic odor. Below boiling point, BD is a colorless liquid with a mildly aromatic odor.

II. Fire, Explosion and Reactivity Hazard Data

A. *Fire.* 1. Flash point: Not applicable (considered a gas for fire purpose).

2. Stability.

3. Flammable limits in air, percent by volume: Lower: 2.0; Upper: 11.5.

4. Extinguishing media: Carbon dioxide for small fires, polymer or alcohol foams for large fires.

5. Special fire fighting procedures: Dilution with 23 volumes of water renders it non-flammable.

6. Unusual fire and explosion hazards: Vapors of BD will burn without the presence of air or other oxidizers. BD vapors are heavier than air and may travel along the ground and be ignited by open flames or sparks at locations remote from the site at which BD is being used.

7. For purposes of compliance with the requirements of 29 CFR 1910.106, BD is classified as a flammable gas. For example, 7,500 ppm, approximately one-fourth of the lower flammable limit, would be considered to pose a potential fire and explosion hazard.

8. For purposes of compliance with 29 CFR 1910.155. BD is classified as a Class B fire hazard.

9. For purposes of compliance with 29 CFR 1910.307, locations classified as hazardous due to the presence of BD shall be Class I.

B. *Reactivity.* 1. Conditions contributing to instability: Heat. Peroxides are formed when inhibitor concentration is not maintained at proper level. At elevated temperatures, such as in fire conditions, polymerization may take place.

2. Incompatibilities: Contact with strong oxidizing agents may cause fires and explosions. Contact with copper and copper alloys may cause formations of explosive copper compounds.

3. Hazardous decomposition products: Toxic gases and vapors (such as carbon monoxide) may be released in a fire involving BD.

4. Special precautions: BD will attack some forms of plastics, rubber, and coatings. BD in storage should be checked for proper inhibitor content, for self-polymerization, and for formation of peroxides when in contact with air and iron. Piping carrying BD may become plugged by formation of rubbery polymer.

C. *Warning Properties.* 1. Odor Threshold: An odor threshold of 0.16 ppm was reported.

2. Eye Irritation Level: Grant states that "allegedly workmen exposed to vapors of BD (concentration or purity unspecified) have complained of irritation of eyes, nasal passages, throat, and lungs. However, a precise quantitative study has shown that even a concentration of 8000 ppm in air produces no symptoms in human beings. Dogs and rabbits exposed experimentally to as much as 6700 ppm 7½ hours a day for 8 months have developed no histologically demonstrable abnormality in any part of the eyes."

3. Evaluation of Warning Properties: Since the odor threshold of BD is well below the permissible exposure limit, it is treated as a material with good warning properties.

III. Spill, Leak, and Disposal Procedures

A. Persons not wearing protective equipment and clothing should be restricted from areas of spills or leaks until cleanup has been completed. If BD is spilled or leaked, the following steps should be taken:

1. Remove all ignition sources.

2. Ventilate areas of spill or leak.

3. In case of liquids containing BD, spills of small quantities can be absorbed on paper towels. Evaporate in a safe place (such as fume hood). Allow sufficient time for evaporating vapors to completely clear the hood ductwork. Burn the paper in a suitable location away from combustible materials. Large quantities can be collected and atomized in a suitable combustion chamber.

4. If in gaseous form, stop flow of gas. If source of leak is a cylinder and the leak cannot be stopped in place, remove the leaking cyclinder to a safe place in the open air and repair the leak or allow the cylinder to empty.

B. BD may be disposed of:

1. If in liquid form, by atomizing in a suitable combustion chamber.

2. If in gaseous form, by burning in a safe location or in a suitable combustion chamber.

IV. Monitoring and Measurement Procedures

A. Exposure above the Permissible Exposure Limit

1. *Eight-hour exposure evaluation.* Measurements taken for the purpose of determining employee exposure under this section are best taken with consecutive samples covering the full shift. Air samples must be taken in the employee's breathing zone (air that would most nearly represent that inhaled by the employee).

2. *Monitoring techniques.* The sampling and analysis under this section may be performed by collection of the BD vapor on charcoal adsorption tubes or other composition adsorption tubes, with subsequent chemical analysis. Sampling and analysis may also be performed by instruments such as real-time continuous monitoring systems, portable direct reading instruments, or passive dosimeters as long as measurements taken using these methods accurately evaluate the concentration of BD in employees breathing zones.

Appendix D describes the validated method of sampling and analysis which has been tested by OSHA for use with BD. The employer has the obligation of selecting a monitoring method which meets the accuracy and precision requirements of the standard under his unique field conditions. The standard requires that the method of monitoring must be accurate, to a 95 percent confidence level, to plus or minus 25 percent for concentrations of BD at or above 2 ppm, and to plus or minus 35 percent for concentrations below 2 ppm. In addition to the method described in appendix D, there are numerous other methods available for monitoring for BD in the workplace. Details on these other methods have been submitted by various companies to the rulemaking record, and are available at the OSHA Docket Office.

B. Since many of the duties relating to employee exposure are dependent on the results of measurement procedures, employers must assure that the evaluation of employee exposure is performed by a technically qualified person.

V. Personal Protective Equipment

A. Employees should be provided with and required to use impervious clothing, gloves, face shields (eight-inch minimum), and other appropriate protective clothing necessary to prevent the skin from becoming frozen by contacting with liquid BD or vessels containing liquid BD.

B. Any clothing which becomes wet with liquid BD should be removed immediately and not reworn until the butadiene has evaporated.

C. Employees should be provided with and required to use splashproof safety goggles where liquid BD may contact the eyes.

VI. Housekeeping and Hygiene Facilities

For purposes of complying with 29 CFR 1910.141, the following items should be emphasized:

A. The workplace should be kept clean, orderly, and in a sanitary condition. The employer is required to institute a leak and spill detection program for operations involving liquid BD in order to detect sources of fugitive BD emissions.

B. Adequate washing facilities with hot and cold water are to be provided, and maintained in a sanitary condition. Suitable cleansing agents are also to be provided to assure the effective removal of BD from the skin.

C. Change or dressing room with individual clothes storage facilities must be provided to prevent the contamination of street clothes with BD. Because of the hazardous nature of BD, contaminated protective clothing should be placed in a regulated area designated by the employer for removal of BD before the clothing is laundered or disposed of.

VII. Miscellaneous Precautions

A. Store BD in tightly closed container in a cool, well-ventilated area and take all necessary precautions to avoid any explosion hazard.

B. Non-sparking tools must be used to open and close metal containers. These containers must be effectively grounded and bonded.

C. Do not incinerate BD cartridges, tanks or other containers.

D. Employers shall advise employees of all areas and operations where exposure to BD occur.

VIII. Common Operations and Controls

The following list includes some common operations in which exposure to BD may occur and control methods which may be effective in each case:

Operations	Controls
Liberation of BD during molding and vulcanizing operations in the processing of rubber products from styrene-butadiene (SBR) elastomer and polybutadiene elastomer into rubber products; manufacture of high-impact polystyrene containing SBR/polybuyadiene elastomer and manufacture of SBR foams; processing into products of ABS resins and styrene-butadiene copolymer resins; processing of neoprene elastomers into rubber products; processing of nitrile elastomer into nitrile latexes and rubbers; processing of nitrile elastomer and PVC-nitrile polyblends into rubber products and calendered plastic products.	General dilution ventilation; local exhaust ventilation.
Use in manufacture of SBR elastomer, polybutadiene elastomer, neoprene elastomer, nitrile elastomer, and SB copolymer and ABS resins.	General dilution; local exhaust ventilation personal protective equipment.
Use in manufacture of adiponitrile, cycloolefins, 1,4-hexadiene tetramethylene-sulfone, and tetrahydro-pthalic anhydride..	General dilution; local exhaust ventilation; personal protective equipment.

Appendix C to § 1910.1051: Medical Surveillance for 1,3-Butadiene

I. Route of Entry

Inhalation.

II. Toxicology

Inhalation of BD has been linked to an increased risk of cancer, damage to the reproductive organs, and fetotoxicity. Butadiene can be converted via oxidation to epoxybutene and diepoxybutane, two genotoxic metabolites that may play a role in the expression of BD's toxic effects.

BD has been tested for carcinogenicity in mice and rats. Both species responded to BD exposure by developing cancer at multiple primary organ sites. Early deaths in mice were caused by malignant lymphomas, primarily lymphocytic originating in the thymus. Epidemiologic evidence in synthetic rubber workers suggests that BD exposure may be associated with an increased risk of lymphomas and leukemias in humans.

Mice exposed to BD at concentrations of 20 ppm or greater developed ovarian or testicular atrophy. Sperm head morphology tests also revealed abnormal sperm in mice exposed to BD; lethal mutations were found in a dominant lethal test. Evidence of teratogenicity was observed in the offspring of female rats exposed to BD. In light of these results in animals, the possibility that BD may adversely affect the reproductive systems of male and female workers must be considered.

Anemia has been observed in animals exposed to butadiene. In some cases, this anemia appeared to be a primary response to exposure; in other cases, it may have been secondary to a neoplastic response. Mild alterations of hematologic parameters have also been observed in synthetic rubber workers exposed to BD.

III. Medical Signs and Symptoms of Acute Exposure

Skin contact with liquified BD causes characteristic burns or frostbite.

At very high concentrations in air, BD is an anesthetic, causing narcosis, respiratory paralysis, unconsciousness, and death. Such concentrations are unlikely, however, except in an extreme emergency because BD poses an explosion hazard at these levels.

At lower air concentrations, BD can irritate the eyes, nasal passages, throat, and lungs. Blurred vision, coughing, and drowsiness may also occur. Effects are mild at 2,000 ppm and pronounced at 8,000 ppm for exposures occurring over the full workshift.

IV. Surveillance and Preventative Consideration

As described above, the principal effects of concern are BD-induced lymphoma, leukemia and reproductive toxicity. Anemia and other changes in the peripheral blood cells may be indicators of excessive exposure to BD.

The proposed medical surveillance program is designed to observe exposed workers on a regular basis. The reporting of symptoms characteristic of lymphoma and the results of a physical examination directed at detection of lymph node enlargement would provide the best opportunity to detect lymphoma at an early stage. A medical surveillance program for detection of bone marrow toxicity would focus on the regular screening of blood indices to detect pathological changes in the hematopoietic system.

Since the potential reproductive effects of BD are not of concern to all workers exposed to this toxic gas, the proposed medical surveillance program would focus consultations and examinations relating to developmental toxicity and reproductive capacity on those workers who have a need to receive such information and testing.

A. Medical and Occupational History

The medical and occupational history would play a prominent role in identification of workers at greatest risk of developingneoplasia or reproductive effects from their exposures to BD.

The most important goal of the proposed medical history would be to elicit information from the worker regarding potential signs or symptoms generally related to the relevant neoplasias, such as non-Hodgkins lymphoma. Physicians should be aware of the presenting symptoms and signs of reticuloendothelial and hematopoietic neoplasia and the procedures necessary to confirm or exclude such a diagnosis.

Workers with a history of reproductive difficulties or a personal or family history of immune deficiency syndromes, blood dyscrasias, lymphoma, or leukemia, and those who are or have been exposed to medicinal drugs or chemicals known to affect the hematopoietic or lymphatic systems may be at higher risk from their exposure to BD.

To assure that subtle changes are identified, the physician would update and review the medical and occupational history of patients exposed to BD each subsequent time an examination or consultation is conducted.

B. Physical Examination

Medical surveillance conducted by a licensed physician would indicate if a worker has blood changes indicative of otherwise unsuspected overexposure to BD or an early stage of leukemia or non-Hodgkins lymphoma. Although neither reticuloendothelial or hematopoietic neoplasia is proven to be induced by BD, sufficient experimental data in animals and suggestive epidemiological data exist to warrant a careful and constant medical surveillance program to anticipate and, if possible, reverse such adverse effects of BD exposure if they occur.

Because of the importance of lung function to workers required to wear respirators to protect themselves from BD exposure, these workers would receive an assessment for pulmonary function before they begin to wear a respirator and at least every three years thereafter. Pulmonary function testing would be conducted by a licensed physician experienced in pulmonary function tests or by persons who have completed a training course in spirometry sponsored by an appropriate governmental, academic, or professional institution to assure reproducibility of results. (Such training is available through the National Institute for Occupational Safety and Health (NIOSH).) Pulmonary function tests conducted would have to be adequate to determine the employee's ability to wear a respirator, and decisions based on these tests should follow established medical criteria for evaluation of pulmonary function.

C. Additional Examinations and Referrals

1. *Examination by a Specialist.* When a worker presents unexplained symptoms or signs in the physical examination or in the laboratory tests, follow-up medical surveillance would be necessary to assure that BD exposure is not adversely affecting the worker's health. Additional tests should be undertaken to determine the nature of the medical problem and the underlying cause. Where relevant, the worker would be sent to a specialist for further testing and treatment as necessary.

2. *Emergencies* The examination of workers exposed to BD in an emergency would be directed at the organ systems most likely to be affected. If the worker has received a severe acute exposure, hospitalization may be required to assure proper medical intervention. It is not possible to define "severe," but the physician's judgment should not merely rest on hospitalization. If the worker has suffered significant conjunctival, oral, or nasal irritation, respiratory distress, or discomfort, the physician should instigate appropriate followup procedures. These include attention to the eyes, the neurological system, and because such individuals may have been placed at greater risk to blood dyscrasias, follow-up examinations of the peripheral blood. An immediate complete blood count should be followed by a similar examination at three, six, and twelve months following the

emergency exposure. This testing would permit the earlyidentification essential to proper medical management of such workers.

3. *Consultations and examinations relating to reproductive toxicity.* The responsible physician would have to be alerted to the needs of workers who are concerned about the possibility that their BD exposure may be affecting their ability to procreate a healthy child. For workers with high exposures to BD, especially those who have experienced difficulties in conceiving, miscarriages, or stillbirths, appropriate medical and laboratory evaluation of fertility may be necessary to determine if BD is having any adverse effect on the reproductive system or on the health of the fetus. In such cases these medical or clinical tests would be identified by the examining physician and conducted accordingly.

D. *Additional Examinations or Tests.* The physician may deem it necessary to perform other medical examinations or tests as indicated. The proposal provides a mechanism whereby these additional investigations would be covered under the standard for occupational exposure to BD, and it also permits physicians to add appropriate or necessary tests to improve the diagnosis of disease should such tests become available in the future.

E. *Employer Obligations:* The employer would be required to provide the responsible physician and any specialists involved in a diagnosis with the following information: A copy of the BD Standard including relevant appendices; a description of the affected employee's duties as they relate to his or her exposure to BD; an estimate of the employee's exposure including duration (e.g. 15 hr/wk, three 8-hour shifts, full time); a description of any personal protective equipment, including respirators used by the employee; and the results of any previous medical determinations for the affected employee related to BD exposure to the extent that this information is within the employer's control.

F. *Physician's Obligations.* The standard would require the employer to cbtain a written statement from the physician. This statement would have to contain the physician's opinion, based on a written evaluation of test results and the physical examination, as to whether the employee has any medical condition placing him or her at increased risk of impaired health from exposure to BD or use of respirators, as appropriate. The physician would also have to state his or her opinion regarding any restrictions that should be placed on the employee's exposure to BD or upon the use of protective clothing or equipment such as respirators. If the employee wears a respirator as a result of his or her exposure to BD, the physician's opinion would have to also contain a statement regarding the suitability of the employee to wear the type of respirator assigned. Finally, the physician would have to inform the employer that the employee has been told the results of the medical examination and of any medical conditions which require further explanation or treatment. This written opinion is not to contain any information on specific findings or diagnoses unrelated to occupational exposure.

The purpose in requiring the examining physician to supply the employer with a written opinion is to provide the employer with a medical basis to assist the employer in placing employees initially, in assuring that their health is not being impaired by BD, and to assess the employee's ability to use any required protective equipment.

Appendix D to § 1910.1051: Sampling and Analytical Method for 1, 3-Butadiene

Methods for 1, 3 Butadiene

A number of methods are available for monitoring employee exposures to BD. Most of these involve the use of charcoal tubes and sampling pumps, followed by analysis of the samples by gas chromatography. The essential differences between the charcoal tube methods include, among others, the use of different desorbing solvents, the use of different lots of charcoal, and the use of different equipment for analysis of the samples.

Besides charcoal, methods using passive dosimeters, gas sampling bags, impingers and detector tubes have been utilized for determination of BD exposure. In addition, there are several commercially available portable gas analyzers and monitoring units.

This appendix contains details for the method which has been tested at the OSHA Analytical Laboratory in Salt Lake City. Inclusion of this method in the appendix does not mean that this method is the only one which will be satisfactory. Copies of descriptions of other methods are available in the rulemaking record, and may be obtained from the OSHA Docket Office. These include the Union Carbide, Dow Chemical, 3M, and Dupont methods, as well as NIOSH Method S-91.

Employers who note problems with sample breakthrough using the OSHA or other charcoal methods should try larger charcoal tubes. Tubes of larger capacity are available. In addition, lower flow rates and shorter sampling times should be beneficial in minimizing breakthrough problems. Whatever method the employer chooses, he must assure himself of the method's accuracy and precision under the unique conditions present in his workplace.

1, 3-Butadiene

Method No.: 56.

Matrix: Air.

Target concentration: 1 ppm (2.21 mg/m^3).

Procedure: Air samples are collected by drawing known volumes of air through sampling tubes containing charcoal adsorbent which has been coated with 4-tert-butylcatechol. The samples are deabsorbed with carbon disulfide and then analyzed by gas chromatography using a flame ionization detector.

Recommended sampling rate and air volume: 0.05 L/min and 3 L.

Detection limit of the overall procedure: 90 ppb (200 ug/m^3) (based on 3 L air volume).

Reliable quantitation limit: 155 ppb (343 ug/m^3) (based on 3 L air volume).

Standard error of estimate at the target concentration: 6.5% (Section 4.6.l).

Special requirements: The sampling tubes must be obtained coated with 4-tert-butylcatchol. Collected samples should be stored in a freezer.

Status of method: A sampling and analytical method that has been subjected to the established evaluation procedures of the Organic Methods Evaluation Branch.

Date: December, 1985.

Chemist: Warren Hendricks.

Organic Methods Evaluation Branch OSHA Analytical Laboratory Salt Lake City, Utah

1. General Discussion

1.1 Background.

1.1.1 History. This work was undertaken to develop a sampling and analytical procedure for 1,3-butadiene at 1 ppm. The 1 ppm target concentration was selected in anticipation of a possible reduction in the current OSHA PEL of 1000 ppm. NIOSH has recently recommended that 1,3-butadiene be treated as a potential occupational carcinogen, teratogen and as a reproduction hazard. (Ref. 5.1)

The current method recommended by OSHA for collecting 1,3-butadiene uses activated coconut shell charcoal as the sampling medium (Ref. 5.2). This method was found to be inadequate for use at low 1,3-butadiene levels because of sample instability (Sections 4.5.2 and 4.6.2).

The stability of samples has been significantly improved through the use of a specially cleaned charcoal which is coated with 4-tert-butylcatechol (TBC). TBC is a polymerization inhibitor for 1,3-butadiene (Ref. 5.3).

1.1.2. Toxic effects (This section is for information only and should not be taken as the basis of OSHA policy). Symptoms of human exposure to 1,3-butadiene include irritation of the eyes, nose and throat. It can also cause coughing, drowsiness and fatigue. Dermatitis and frostbite can result from skin exposure to liquid 1,3-butadiene. (Ref. 5.1)

NIOSH recommends that 1,3-butadiene be handled in the workplace as a potential occupational carcinogen. This recommendation is based on two inhalation studies that resulted in cancers at multiple sites in rats and in mice. 1,3-butadiene has also demonstrated mutagenic activity in the presence of a liver microsomal activating system. It has also been reported to have adverse teratogenic and reproductive effects. (Ref. 5.1)

1.1.3 Potential workplace exposure. In 1984, 2.53 billion pounds of rubber grade butadiene were produced. This amount was only 3.7% less than the average yearly amount produced during the past decade of 1974–1984. In 1984, butadiene ranked 36th of the top 50 chemicals produced in the U.S. (Ref. 5.4) About 80% of the 1,3-butadiene produced in the United States is a by-product of the manufacture of ethylene. The remaining 20% is produced by the dehydrogenation of n-butene and n-butane. (Ref. 5.1)

About 90% of the annua' production of 1,3-butadiene is used to manutacture styrene-butadiene rubber and polybutadiene rubber. Other uses include: polychloroprene rubber, acrylonitrile butadiene-styrene resins, nylon intermediates, styrene-butadiene latexes, butadiene polymers, thermoplastic

elastomers, nitrile resins, methyl methacrylate-butadiene styrene resins and chemical intermediates. (Ref. 5.1)

A NIOSH survey, that was conducted from 1972 to 1974, estimated that approximately 65,000 workers were potentially exposed to 1,3-butadiene. About 70% of this total was employed in chemical and chemical products occupations. Another 25% of the total was employed in workplaces which included: rubber and rubber products industries, miscellaneous business services and miscellaneous manufacturing industries. (Ref. 5.1)

1.1.4 *Physical properties (Ref. 5.1).*

CAS No.: 106–99–0.

Molecular weight: 54.1.

Appearance: Colorless gas.

Boiling point: -4.41 °C (760 mm Hg).

Freezing point: -108.9 °C.

Vapor pressure: 2 atm @ 15.3 °C; 5 atm @ 47. °C.

Explosive limits: 2 to 11.5% (by volume) (in air)

Odor threshold: 1.3 ppm.

Structural formula: $H_2C:CHCH:CH_2$

Synonyms: biethylene; bivinyl; butadiene; divinyl; buta-1,3-diene;

alpha-gama-butadiene; erythrene; NCI–C50602; pyrrolylene; vinylethylene.

1.2 Limit defining parameters.

The analyte air concentrations listed throughout this method are based on an air volume of 3 L and a desorption volume of l mL. Air concentrations listed in ppm are referenced to 25 °C and 760 mm Hg.

1.2.1 *Detection limit of the analytical procedure.* The detection limit of the analytical procedure was 304 pg per injection. This was the amount of 1,3-butadiene which gave a measurable response relative to the interferences present in a standard. (section 4.1)

1.2.2 *Detection limit of the overall procedure.* The detection limit of the overall procedure was 0.60 ug per sample (90 ppb or 200 ug/m^3). This amount was determined graphically. It was the amount of analyte which, when spiked on the sampling device, would allow recovery approximately equal to the detection limit of the analytical procedure. (section 4.1.2)

1.2.3 *Reliable quantitation limit.* The reliable quantitation limit was 1.03 ug per sample (155 ppb or 343 ug/m^3). This was the smallest amount of analyte which could be quantitated within the limits of a recovery of at least 75% and a precision (±1.96 SD) of ±25% or better. (section 4.2)

The reliable quantitation limit and detection limits reported in the method are based upon optimization of the instrument for the smallest possible amount of analyte. When the target concentration of an analyte is exceptionally higher than these limits, they may not be attainable at the routine operation parameters.

1.2.4 *Sensitivity.* The sensitivity of the analytical procedure over a concentration range representing 0.6 to 2 times the target concentration, based on the recommended air volume, was 387 area units per ug/mL. This value was determined from the slope of the calibration curve. (section 4.3) The sensitivity may vary with the particular instrument used in the analysis.

1.2.5 *Recovery.* The recovery of 1,3-Butadiene from samples used in storage tests remained above 77% when the samples were stored at ambient temperature and above 94% when the samples were stored at refrigerated temperature. These values were determined from regression lines which were calculated from the storage data. (section 4.6) The recovery of the analyte from the collection device must be at least 75% following storage.

1.2.6 *Precision (analytical method only).* The pooled coefficient of variation obtained from replicate determinations of analytical standards over the range of 0.6 to 2 times the target concentration was 0.011. (section 4.3)

1.2.7 *Precision (overall procedure).* The precision at the 95% confidence level for the refrigerated temperature storage test was ±12.7%. (section 4.6.1) This value includes an additional ±5% for sampling error. The overall procedure must provide results at the target concentrations that are ±25% at the 95% confidence level.

1.2.8 *Reproducibility.* Samples collected from a controlled test atmosphere and a draft copy of this procedure were given to a chemist unassociated with this evaluation. The average recovery was 97.2% and the standard deviation was 6.2%. (section 4.7)

1.3 Advantages

1.3.1 The sampling and analytical procedure permits determination of 1,3-butadiene at low-levels.

1.3.2 Samples are relatively stable following storage for at least 17 days.

1.4 Disadvantage

The recommended sampling tubes must be obtained from the Salt Lake City Analytical Laboratory.

2. *Sampling procedure*

2.1 Apparatus

2.1.1 Samples are collected by use of a personal sampling pump that can be calibrated to within ±5% of the recommended 0.05 L/min sampling rate with the sampling tube in line.

2.1.2 Samples are collected with laboratory prepared sampling tubes.

The sampling tube is constructed of silane-treated glass and is about 5-cm long. The ID is 4 mm and the OD is 6 mm. One end of the tube is tapered so that a glass wool end plug will hold the contents of the tube in place during sampling. The opening in the tapered end of the sampling tube is at least one-half the ID of the tube (2 mm). The other end of the sampling tube is open to its full 4-mm ID to facilitate packing of the tube. Both ends of the tube are fire-polished for safety. The tube is packed with 2 sections of pretreated charcoal which has been coated with TBC. The tube is packed with a 50-mg backup section, located nearest the tapered end, and with a 100-mg sampling section of charcoal. The two sections of coated adsorbent are separated and retained with small plugs of silanized glass wool. Following packing, the sampling tubes are sealed with two 7/32 inch OD plastic end caps. Instructions for the pretreatment and coating of the charcoal are presented in section 4.8 of this method.

2.2 Reagents

None required.

2.3 Technique

2.3.1 Properly label the sampling tube before sampling and then remove the plastic end caps.

2.3.2 Attach the sampling tube to the pump using a section of flexible plastic tubing such that the larger front section of the sampling tube is exposed directly to the atmosphere. Do not place any tubing ahead of the sampling tube. The sampling tube should be attached in the worker's breathing zone in a vertical manner such that it does not impede work performance.

2.3.3 After sampling for the appropriate time, remove the sampling tube from the pump and then seal the tube with plastic end caps. Wrap the tube lengthwise with an official OSHA seal (Form 21).

2.3.4 Include at least one blank for each sampling set. The blank should be handled in the same manner as the samples with the exception that air is not drawn through it.

2.3.5 List any potential interferences on the sample data sheet.

2.3.6 The samples require no special shipping precautions under normal conditions. The samples should be refrigerated if they are to be exposed to higher than normal ambient temperatures. If the samples are to be stored before they are shipped to the laboratory, they should be kept in a freezer. The samples should be placed in a freezer upon receipt at the laboratory.

2.4 Breakthrough (Breakthrough was defined as the relative amount of analyte found on the backup section of the tube in relation to the total amount of analyte collected on the sampling tube.)

Five-percent breakthrough occurred after sampling a test atmosphere containing 2.0 ppm 1,3-butadiene for 90 min at 0.05 L/min. At the end of this time 4.5 L of air had been sampled and 20.1 ug of the analyte was collected. The relative humidity of the sampled air was 80% at 23 °C. (section 4.4)

Breakthrough studies have shown that the recommended sampling procedure can be used at air concentrations higher than the target concentration. The sampling time, however, should be reduced to 45 min if both the expected 1,3-butadiene level and if the relative humidity of the sampled air are high. (section 4.4)

2.5 Desorption efficiency.

The average desorption efficiency for 1,3-butadiene from TBC coated charcoal over the range from 0.6 to 2 times the target concentration was 96.4%. The desorption efficiency was essentially constant over the range studied. (section 4.5)

2.6 Recommended air volume and sampling rate

2.6.1 The recommended air volume is 3 L.

2.6.2 The recommended sampling rate is 0.05 L/min for l hour.

2.7 Interferences

There are no known interferences to the sampling method.

2.8 Safety precautions

2.8.1 Attach the sampling equipment to the worker in such a manner that it will not interfere with work performance or safety.

2.8.2 Follow all safety practices that apply to the work area being sampled.

3. *Analytical procedure*

3.1 Apparatus

3.1.1 A gas chromatograph (GC), equipped with a flame ionization detector (FID). A

Hewlett-Packard Model 5840A GC was used for this evaluation. Injections were performed using a Hewlett-Packard Model 7671A automatic sampler.

3.1.2 A GC column capable of resolving the analytes from any interference. A 20 ft × ⅛ in OD stainless steel GC column containing 20% FFAP on 80/100 mesh Chromabsorb W-AW-DMCS was used for this evaluation.

3.1.3 Vials, glass 2-mL with Teflon-lined caps.

3.1.4 Disposable Pasteur-type pipets, volumetric flasks, pipets and syringes for preparing samples and standards, making dilutions and performing injections.

3.2 Reagents

3.2.1 *Carbon disulfide.* Fisher Scientific Company A.C.S. Reagent Grade solvent was used in this evaluation.

The benzene contaminant that was present in the carbon disulfide was used as an internal standard [ISTD] in this evaluation.

3.2.2 Nitrogen, hydrogen and air, GC grade.

3.2.3 1,3-butadiene of known high purity. Matheson Gas Products, CP Grade 1,3-butadiene was used in this study.

3.3 Standard preparation

3.3.1 Prepare standards by diluting known volumes of 1,3-butadiene gas with carbon disulfide. This can be accomplished by injecting the appropriate volume of 1,3-butadiene into the headspace above the 1-mL of carbon disulfide contained in sealed 2-mL vial. Shake the vial after the needle is removed from the septum. A standard containing 7.71 μg/mL (at ambient temperature and pressure) was prepared by diluting 4 μL of the gas with 1-mL of carbon disulfide.

3.3.2 The mass of 1,3-butadiene gas which was used to prepare standards can be determined by use of the following equations:

$MV = (760/BP)(273+t)/(273)(22.41)$

Where:

MV = ambient molar volume
BP = ambient barometric pressure
T = ambient temperature
μg/μL = 54.09/MV
μg/standard = (μg/μL)(μL) 1,3-butadiene used to prepare the standard

3.4 Sample preparation

3.4.1 Transfer the 100-mg section of the sampling tube to a 2-mL vial. Place the 50-mg section in a separate vial. If the glass wool plugs contain a significant amount of charcoal, place them with the appropriate sampling tube section.

3.4.2 Add 1 mL of carbon disulfide to each vial.

3.4.3 Seal the vials with Teflon-lined caps and then allow them to deabsorb for one hour. Shake the vials by hand with vigorous force several times during the desorption time.

3.4.4 If it is not possible to analyze the samples within 4 hours of desorption, separate the carbon disulfide from the charcoal, using a disposable Pasteur-type pipet, following the one hour desorption time. This separation will improve the stability of deabsorbed samples. (Tables 4.5.1.2 and 4.5.1.3)

3.4.5 Save the used sampling tubes to be cleaned and repacked with fresh adsorbent.

3.5 Analysis

3.5.1 GC Conditions

Column temperature: 95 °C
Injector temperature: 180 °C
Detector temperature: 275 °C
Carrier gas flow rate: 30 mL/min
Injection volume: 0.80 μL
GC column: 20-ft × ⅛-in OD stainless steel GC column containing 20% FFAP on 80/100 Chromabsorb W-AW-DMCS.

3.5.2 Chromatogram. See Backup Data section 4.9.

3.5.3 Use a suitable method, such as electronic integration or peak heights, to measure detector response.

3.5.4 Prepare a calibration curve using several standard solutions of different concentrations. Prepare the calibration curve daily. Program the integrator to report the results in μg/mL.

3.5.5 Bracket sample concentrations with standards.

3.6 Interferences (analytical)

3.6.1 Any compound with same general retention time as the analyte and which also gives a detector response is a potential interference. Possible interferences should be reported to the laboratory with submitted samples by the industrial hygienist.

3.6.2 GC parameters (temperature, column, etc.) may be changed to circumvent interferences.

3.6.3 A useful means of structure designation is GC/MS. It is recommended that this procedure be used to confirm samples whenever possible.

3.7 Calculations

3.7.1 Results are obtained by use of calibration curves. Calibration curves are prepared by plotting detector response against concentration for each standard. The best line through the data points is determined by curve fitting.

3.7.2 The concentration, in μg/mL, for a particular sample is determined by comparing its detector response to the calibration curve. If any analyte is found on the backup section, this amount is added to the amount found on the front section. Blank corrections should be performed before adding the results together.

3.7.3 The 1,3-butadiene air concentration can be expressed using the following equation:

$mg/m^3 = (A)(B)/(C)(D)$

Where:

A = μg/mL from section 3.7.2
B = desorption volume
C = L of air sampled
D = desorption efficiency

3.7.4 The following equation can be used to convert results in mg/m^3 to ppm:

$ppm = (mg/m^3)(24.46)/54.09$

Where:

mg/m^3 = result from section 3.7.3.
24.46 = molar volume of an ideal gas at 760 mm Hg and 25 °C.

3.8 Safety precautions (analytical)

3.8.1 Avoid skin contact and inhalation of all chemicals.

3.8.2 Restrict the use of all chemicals to a fume hood whenever possible.

3.8.3 Wear safety glasses and a lab coat in all laboratory areas.

4. *Backup Data*

4.1 Detection limit data

4.1.1 *Detection limit of analytical procedure.* The injection size recommended in the analytical procedure (0.80 μL) was used in the determination of the detection limit for the analytical procedure. The detection limit for the analytical procedure was 304 pg per injection. This was the amount of 1,3-butadiene which gave a measurable response relative to interferences present in a standard. This detection limit was determined by the analysis of a standard containing 380 ng/mL 1,3-butadiene. Fig. 4.1.1. is a chromatogram of the detection limit of the analytical procedure.

4.1.2 *Detection limit of the overall procedure.* The injection size recommended in the analytical procedure (0.80 μL) was used in the determination of the detection limit of the overall procedure. 1,3-butadiene was diluted for use in this study by adding pure analyte to a sealed, silanized vial containing air and a few crystals of TBC. Samples were prepared by injecting 100-mg portions of TBC coated charcoal with appropriate amounts of the diluted 1,3-butadiene. The samples were stored in a freezer overnight before analysis to allow complete adsorption of the analyte. Each result is the average of at least 2 samples. The results of this study are presented in Table 4.1.2 and in Fig. 4.1.2.

4.2 Reliable quantitation limit data

The injection size recommended in the analytical procedure (0.80 μL) was used in the determination of the reliable quantitation limit (RQL). The amount of 1,3-butadiene which provided a recovery of 75% from the sampling media was determined graphically (Fig. 4.2.1) from the data in Table 4.1.2. This amount was 1.03 μg. A chromatogram of the RQL is presented in Fig. 4.2.2. Six samples were used to determine the precision at the RQL. The samples were prepared in a similar manner as those in section 4.1.2. The results of this study are presented in Table 4.2. and in Fig. 4.2.1.

4.3 Sensitivity and precision (analytical method only)

The sensitivity and precision of the analytical procedure were evaluated by performing multiple injections of analytical standards. The standards were prepared by injecting appropriate amounts of 1,3-butadiene gas diluted with carbon disulfide. The data are presented in Table 4.3. and also in Fig. 4.3. The ISTD data are the results of an internal standard calibration using the benzene contaminant present in carbon disulfide as the internal standard.

TABLE 4.1.2—DETECTION LIMIT DATA

Sample No.	μg spiked	μg recovered	Percent recovered
1	0.38	0.26	68.4
2	0.58	0.34	58.6
3	0.76	0.48	63.2
4	0.96	0.67	69.8
5	1.2	1.0	83.3
6	1.4	1.3	92.8
7	1.9	1.9	100.0

The detection limit of the overall procedure was determined graphically (Fig. 4.1.2.) from the data in Table 4.1.2. This amount was 0.60 μg per sample.

TABLE 4.2.—RELIABLE QUANTITATION LIMIT DATA

	Sample No.	μg spiked	μg recovered	Percent recovered
	1	1.03	0.854	82.9
	2	1.03	0.754	73.2
	3	1.03	0.829	80.5
	4	1.03	0.779	75.6
	5	1.03	0.836	81.2

TABLE 4.2.—RELIABLE QUANTITATION LIMIT DATA —Continued

	Sample No.	μg spiked	μg recovered	Percent recovered
	6	1.03	0.836	81.2
X		1.03	0.815	79.1
SD				3.8
1.96 SD				7.4

TABLE 4.3—1,3-BUTADIENE SENSITIVITY AND PRECISION DATA

	0.6X		1X		2X	
	3.86 μg/sample		6.75 μg sample		13.5 μg sample	
	ISTD	area	ISTD	area	ISTD	area
	3.85	1332	6.66	2371	13.4	5190
	3.89	1509	6.73	2386	13.5	5167
	3.85	1507	6.78	2369	13.7	5076
	3.81	1345	6.78	2393	13.5	5097
	3.81	1416	6.86	2529	13.6	5045
	3.95	1354	6.75	2327	13.3	5087
X	3.86		6.76		13.5	
CV	0.0138		0.00977		0.0105	
CV	0.011					

The sensitivity for 1,3-butadiene was 387 area counts per μg/mL.

4.4 Breakthrough data

Breakthrough was defined as the relative amount of 1,3-butadiene found on the 50 mg sampling tube section in relation to the total amount collected on the sampling tube.

Three breakthrough studies were performed at twice the target level with the recommended air sampler. The test atmospheres were generated by diluting the effluent of a gas cylinder containing 100 ppm 1,3-butadiene with humid air. The concentrations of the test atmospheres were determined by direct injection of the atmosphere into a gas chromatograph. The gas chromatograph was calibrated using 1,3-butadiene from another source that had been diluted with dry air in a Teflon gas bag. The average concentration of the test atmospheres was 2.0 ppm. The average relative humidity of these test atmospheres was 80% at 23 °C. The sampling rates were about 0.05 L/min. The results of these studies are presented in Table 4.4.1.

Additional breakthrough studies were performed at concentrations higher than twice the target level in order to determine if the recommended sampling procedure would be reliable at those concentrations. The test atmospheres used in these studies were generated and their concentrations were determined using the techniques previously described.

TABLE 4.4.1—1,3-BUTADIENE BREAKTHROUGH AT TWICE THE TARGET CONCENTRATION

Sampling time, min	Amt. on 100 mg section, μg	Amt. on 50 mg section, μg	Percent breakthrough
91	23.4	0.0	0.0
124	27.8	3.1	10.0
155	30.4	6.1	16.7
60	14.6	0.0	0.0
91	21.6	1.2	5.3
121	25.5	3.5	12.1
50	8.6	0.0	0.0
76	13.0	0.0	0.0
92	14.4	0.6	4.0
105	15.7	2.2	12.3
125	17.0	2.4	12.4

When the results of the three studies were combined, 5% breakthrough occurred after sampling for 90 minutes. The air volume sampled after this time was 4.5 L and the amount of 1,3-butadiene collected was 20.1 μg.

Percent recovery values were calculated using sample results and the actual concentration of the test atmospheres. The sampling rates were about 0.05 L/min. The results of these studies are presented in Tables 4.4.2 through 4.4.4.

4.5 Desorption efficiency and stability of deabsorbed samples

4.5.1 *Preteated charcoal coated with TBC.* The desorption efficiency of 1,3-butadiene was determined by injecting the gas onto 100-mg portions of the recommended collection medium. The samples were spiked and then stored in a freezer overnight prior to analysis. The average desorption efficiency over the range of 0.6 to 2 times the target concentration was 96.4%. The individual results are presented in Table 4.5.1.1.

The stability of deabsorbed samples was investigated by reanalyzing the target concentration desorption samples at various times after carbon disulfide addition. Freshly prepared standards were used for each analysis. The sample vials were resealed immediately after each analysis. The results of this study are presented in Table 4.5.1.2. The percent recovery is based on the theoretical amount of 1,3-butadiene added to the original samples.

TABLE 4.4.2—1,3-Butadiene Breakthrough Study at 7.3 PPM

[Relative Humidity = 77% at 22 °C]

Sampling time, min	Air volume sampled, L	Percent breakthrough	Percent recovery
15	0.73	0.0	80.2
30	1.6	0.0	94.2
45	2.2	0.0	96.8
60	3.1	0.0	99.4
75	3.5	0.6	96.7
90	4.5	8.4	95.8

Five percent breakthrough occurred after sampling for 84 min. At the end of this time, 4.2 L of air had been sampled and 68 ug of 1,3-butadiene had been collected.

TABLE 4.4.3—1,3-Butadiene Breakthrough Study at 32 PPM

[Relative humdity = 47% at 240°C]

Sampling time, min	Air volume sampled L	Percent breakthrough	Percent recovery
15	0.71	0.0	87.3
46	2.3	0.0	87.2
60	3.2	0.0	91.2

TABLE 4.4.3—1,3-Butadiene Breakthrough Study at 32 PPM—Continued

[Relative humdity = 47% at 240°C]

Sampling time, min	Air volume sampled L	Percent breakthrough	Percent recovery
90	4.3	0.0	94.8
105	5.2	0.0	95.0
120	6.3	0.0	97.5
155	8.2	0.0	93.0

No breakthrough was observed, even after sampling for 155 minutes. This data shows that, at low relative humidity, the recommended sampling media has considerable capacity for 1,3-butadiene.

TABLE 4.4.4—1,3-Butadiene Breakthrough Study at 36-ppm

[Relative humdity = 90% at 21°C]

Sampling time, min	Air volume sampled, L	Percent breakthrough	percent recovery
36	1.9	0.0	105.8
47	2.2	0.0	98.8
60	3.0	21.6	90.2
75	3.9	30.0	96.0
90	4.3	30.6	76.4
105	5.8	32.1	57.6
121	6.3	31.1	56.7

It is apparent from the data in Tables 4.4.2 through 4.4.4 that the recommended sampling and analytical method can be used at 1,3-butadiene levels higher than the target concentration. The relative humidity of the sampled air has a significant effect on the ability of the sampling device to retain the analyte.

TABLE 4.5.1.1—THE DESORPTION EFFICIENCY OF 1,3-BUTADIENE FROM CHARCOAL COATED WITH TBC

	Percent desorption efficiency		
	3.86 μg 0.6X	6.75 μg 1.0X	13.5 μg 2.0
	94.3	100.0	97.5
	95.4	97.0	97.5
	96.4	102.0	95.8
	96.9	96.0	95.2
	94.8	94.3	93.4
	96.9	98.8	92.5
	95.8	98.0	95.3
X	95.5	98.0	95.3

TABLE 4.5.1.2—THE STABILITY OF 1,3-BUTADIENE AFTER DESORPTION FROM CHARCOAL COATED WITH TBC

Hours after CS addition	Sample number (percent recovery)						
	1	2	3	4	5	6	X
1	100.0	97.0	102.0	96.0	94.3	98.8	98.0
4	98.7	95.1	97.7	89.0	88.6	87.4	92.8
9	90.2	89.4	92.2	88.7	88.0	89.4	89.6
16	84.2	82.2	84.1	81.3	80.3	86.6	83.1
24	82.4	76.8	79.7	76.6	72.3	79.0	77.8
58	66.8	50.4	52.3	61.5	60.6	64.2	59.3

To determine if the stability of deabsorbed samples could be improved, the following experiment was performed: Twelve samples were prepared by injecting 1,3-butadiene gas, at the target concentration, onto 100-mg portions of the recommended sampling media. The samples were spiked and then stored in a freezer overnight prior to analysis. Following deabsorption and analysis, the carbon disulfide was separated from the charcoal for six of the samples. The other six samples were not separated. All of the samples were reanalyzed using freshly prepared standards and the results of this study are presented in Table 4.5.1.3.

TABLE 4.5.1.3—EFFECT OF CHARCOAL ON THE STABILITY OF 1,3-BUTADIENE IN CS_2

Storage time	CS_2/charcoal separated				CS_2/charcoal not separated			
h	1	2	3	X	1	2	3	X
6	93.1	91.8	93.5	92.8	93.6	91.3	93.1	92.7
28	88.9	90.1	92.4	90.5	76.8	74.0	76.2	75.7

It appears that the stability of desorbed samples can be improved by separating the carbon disulfide from the charcoal.

4.5.2 Untreated charcoal. The desorption efficiency of 1,3-butadiene was also determined for untreated SKC, Inc. Lot 120 coconut shell charcoal in the same manner as used for the recommended medium. The average desorption efficiency over the range of 0.6 to 2 times the target concentration was 60.4%. The individual results are presented in Table 4.5.2.1.

The stability of 1,3-butadiene desorped from untreated SKC, Inc. Lot 120 charcoal was investigated in the same manner as was the recommended medium. The results of this study are presented in Table 4.5.2.2.

4.6 Storage data.

4.6.1 *Pretreated charcoal coated with TBC.* The test atmosphere was generated by diluting the effluent of a gas cylinder, containing 100 ppm 1,3-butadiene, with humid air. The resultant atmosphere contained 1 ppm 1,3-butadiene, the relative humidity of the air was 75% and its temperature was 25°C.

The 1,3-butadiene content of the test atmosphere was determined by direct injection of 100 uL of the atmosphere into a gas chromatograph. The gas chromatograph was calibrated using 1,3-butadiene, from another source, which had been diluted with dry air in a Teflon gas bag. Samples were collected, using the recommended method, and they were stored either at —25sC or at ambient temperature. The results of the storage test are presented in Table 4.6.1 and also in Figures 4.6.1.1 and 4.6.1.2.

TABLE 4.5.2.1—THE DESORPTION EFFICIENCY OF 1,3-BUTADIENE FROM SKC, INC. LOT 120 CHARCOAL

	Percent desorption efficiency		
	3.86 μg 0.6X	6.75 μg 1.0X	13.5 μg 2.0X
	61.6	67.3	67.1
	66.7	64.1	65.0
	61.5	61.7	62.8
	54.4	62.0	61.4
	52.3	57.9	58.7
	51.7	53.3	58.8
X	58.0	61.0	62.3

TABLE 4.5.2.2—THE STABILITY OF 1,3-BUTADIENE AFTER DESORPTION FROM SKC, INC. LOT 120 CHARCOAL

Hours after $CS_{2(g)}$ addition	sample number						
	1	2	3	4	5	6	X
5	43.8	44.0	40.1	40.6	38.8	38.4	41.0

These data show that SKC, Inc. Lot 120 charcoal is inadequate for this application because of sample instability.

TABLE 4.6.1—1,3-BUTADIENE STORAGE TEST USING TBC COATED CHARCOAL

Storage time, days	Ambient recovery			Storage time, days	Refrigerated recovery		
	Percent	Percent	Percent		Percent	Percent	Percent
0	102.2	102.2	99.1	0	97.0	101.8	97.8
3	97.8	93.3	93.3	4	99.5	96.9	98.7
6	100.9	98.7	100.9	7	93.2	104.9	102.2
10	93.8	87.5	83.9	11	98.6	94.6	92.4
13	82.1	88.8	80.8	14	104.1	96.9	98.2
17	81.2	76.3	76.8	18	84.3	94.6	96.4

4.6.2 *Untreated charcoal.* An additional ambient temperature storage test was performed using untreated SKC, Inc. Lot 120 charcoal as sampling media. The test atmosphere was generated and its concentration determined in the same manner as was used for the recommended method. The concentration of the test atmosphere was 1 ppm. The relative humidity of this atmosphere was 70% at 23°C. Sampling was performed at 0.05 L/min for 1 hour. The results of this study are presented in Table 4.6.2 and also in Fig. 4.6.2.

4.7 Reproducibility data

Samples were collected from a test atmosphere which was generated by diluting the effluent of a gas cylinder, containing 100 ppm 1,3-butadiene, with humid air. The resultant atmosphere contained 1 ppm 1,3-butadiene and the relative humidity of the air was 84% at 23°C. The 1,3-butadiene content of the test atmosphere was determined by the direct injection of 100 uL of the atmosphere into a GC. The GC was calibrated using 1,3-butadiene, from another source, which had been diluted with dry air in a Teflon gas bag. The samples and a draft copy of this evaluation were given to a chemist unassociated with this work. The samples were analyzed after 3 days storage at reduced temperature. The results are presented in Table 4.7.

TABLE 4.6.2—1,3-BUTADIENE AMBIENT TEMPERATURE STORAGE TEST USING SKC, INC. LOT 120 CHARCOAL

Storage time, days	Sample number (percent recovery)		
	1	2	3
0	33.5	36.3	33.5
3	31.3	30.1	29.0
6	17.9	12.8	14.9
10	29.0	22.5	22.6
13	25.2	23.8	19.9
17	18.2	19.8	17.4

TABLE 4.7—REPRODUCIBILITY

Number	Sample percent recovery
1	100.0
2	102.9
3	100.5
4	98.0
5	96.6
6	85.4
x	97.2
SD	6.2

4.8 A procedure to prepare specially cleaned charcoal coated with TBC

4.8.1 *Apparatus.*

4.8.1.1 Magnetic stirrer and stir bar.

4.8.1.2 Tube furnace capable of maintaining a temperature of 700°C and equipped with a quartz tube that can hold 30 g of charcoal. A Lindberg Type 55035 tube furnace was used in this evaluation.

4.8.1.3 A means to purge nitrogen gas through the charcoal inside the quartz tube.

4.8.1.4. Water bath capable of maintaining a temperature of 60°C.

4.8.1.5. Miscellaneous laboratory equipment: One-liter vacuum flask, 1-L Erlenmeyer flask, 350-mL Buchner funnel with a coarse fitted disc, 4-oz brown bottle, rubber stopper, Teflon tape etc.

4.8.2. *Reagents.*

4.8.2.1 Phosphoric acid, 10% by weight, in water. "Baker Analyzed" Reagent grade was diluted with water for use in this evaluation.

4.8.2.2. 4-tert-Butylcatechol (TBC). The Aldrich Chemical Company 99% grade was used in this evaluation. CAUTION-The bottle was labeled: Sensitizer! Severe irritant! Toxic! Refrigerate!

4.8.2.3. Specially cleaned coconut shell charcoal, 20/40 mesh. Specially cleaned charcoal (Lot number 482338) was obtained from Supelco, Inc. for use in this evaluation. The cleaning process used by Supelco is proprietary.

4.8.2.4. Nitrogen gas, GC grade.

4.8.3. Procedure. Weigh 30 g of charcoal into a 500-mL Erlenmeyer flask. Add about 250 mL of 10% phosphoric acid to the flask and then swirl the mixture. Stir the mixture for 1 hour using a magnetic stirrer. Filter the mixture using a fitted Buchner funnel. Wash the charcoal several times with 250-mL portions of deionized water to remove all traces of the acid. Transfer the washed charcoal to the tube furnace quartz tube. Place the quartz tube in the furnace and then connect the nitrogen gas purge to the tube. Fire the charcoal to 700°C. Maintain that temperature for at least 1 hour. After the charcoal has cooled to room temperature, transfer it to a tared beaker. Determine the weight of the charcoal and then add an amount of TBC which is 10% of the charcoal, by weight. CAUTION-TBC is toxic and should only be handled in a fume hood while wearing gloves. Carefully mix the contents of the beaker and then transfer the mixture to a 4-oz bottle. Stopper the bottle with a clean rubber stopper which has been wrapped with Teflon tape. Clamp the bottle in a water bath so that the water level is above the charcoal level. Gently heat the bath to 60°C and then maintain that temperature for 1 hour. Cool the charcoal to room temperature and then transfer the coated charcoal to a suitable container.

The coated charcoal is now ready to be packed into sampling tubes. The sampling tubes should be stored in a sealed container to prevent contamination. Sampling tubes

should be stored in the dark at room temperature. The sampling tubes should be segregated by coated adsorbent lot number.

4.9 Chromatograms

The chromatograms were obtained using the recommended analytical method. The chart speed was set at 1 cm/min for the first three min and then at 0.2 cm/min for the time remaining in the analysis.

Figs. 4.2.2. and 4.9.2 are chromatograms of 1,3-butadiene deabsorbed from the recommended sampling media. The peak which eluted just before 1,3-butadiene is a reaction production between an impurity on the charcoal and TBC. This peak is always present, but it is easily resolved from the analyte. The peak which eluted immediately before benzene is an oxidation product of TBC.

5. References

5.1. "Current Intelligence Bulletin 41, 1,3-Butadiene", U.S. Dept. of Health and Human Services, Public Health Service, Center for Disease Control, NIOSH.

5.2. "NIOSH Manual of Analytical Methods", 2nd ed; U.S. Dept. of Health Education and Welfare, National Institute for Occupational Safety and Health: Cincinnati, OH. 1977, Vol. 2, Method No. S91 DHEW (NIOSH) Publ. (US), No. 77–157–B.

5.3. Hawley, G.C., Ed. "The Condensed Chemical Dictionary", 8th ed.; Van Nostrand Rienhold Company: New York, 1971; 139.5.4. *Chem. Eng. News* (June 10, 1985), (63), 22–66.

BILLING CODE 4510-26-M

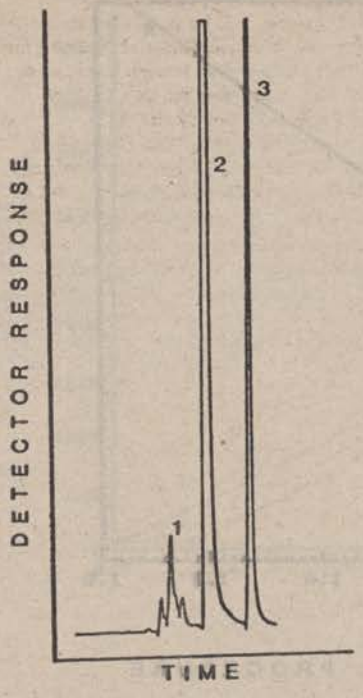

FIG. 4.1.1. DETECTION LIMIT CHROMATOGRAM

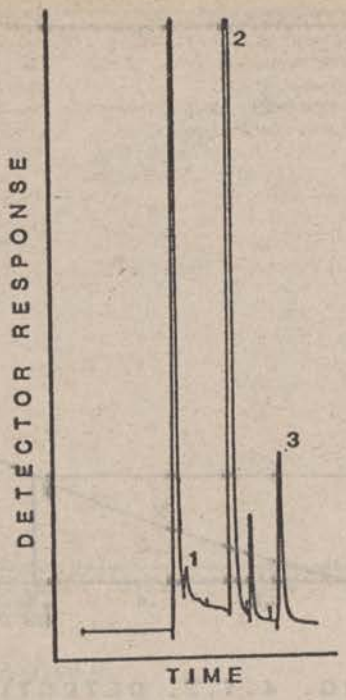

FIG. 4.2.2. RQL CHROMATOGRAM

PEAK IDENTIFICATION

peak number	peak identity	RT, min
1	1,3-butadiene	2.3
2	carbon disulfide	4.2
3	benzene	9.2

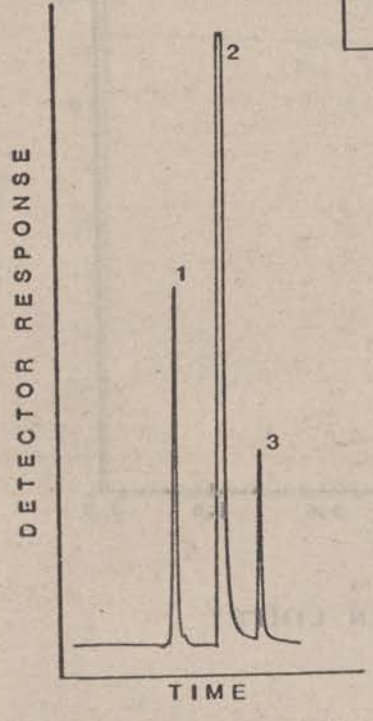

FIG. 4.9.1. STANDARD CHROMATOGRAM

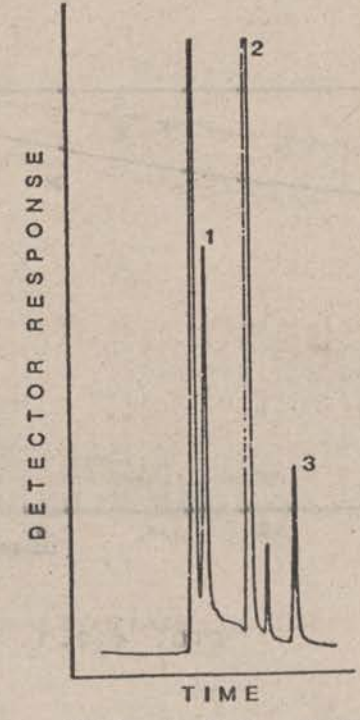

FIG. 4.9.2. SAMPLE CHROMATOGRAM

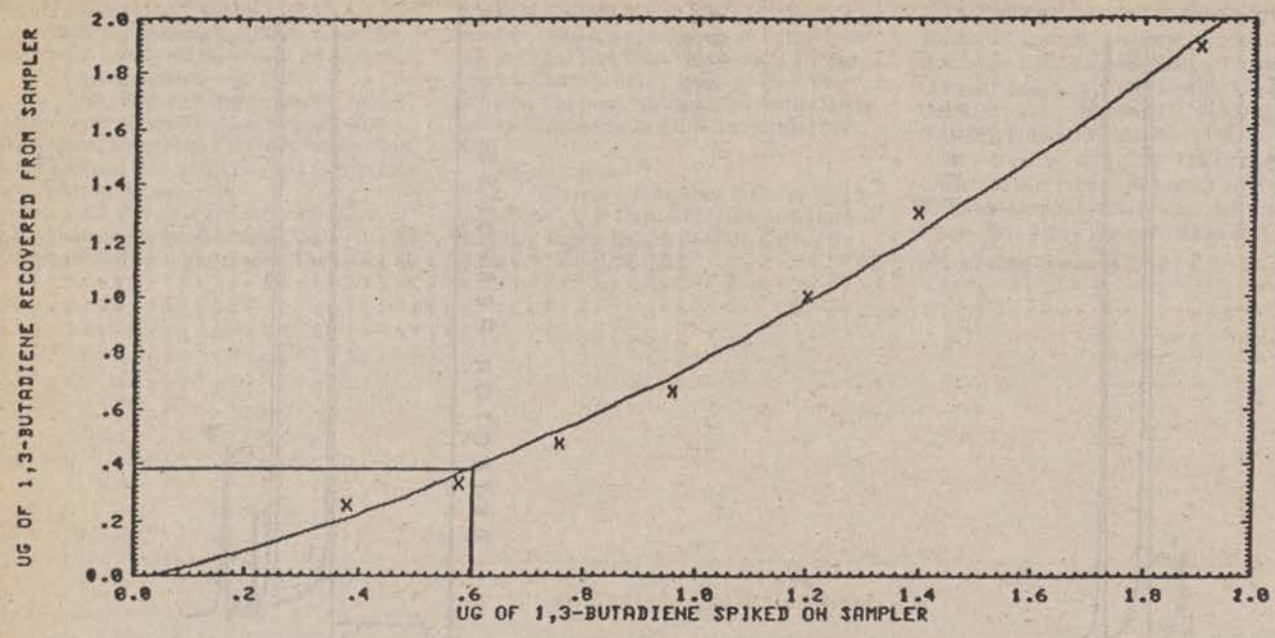

FIG. 4.1.2. DETECTION LIMIT OF THE OVERALL PROCEDURE

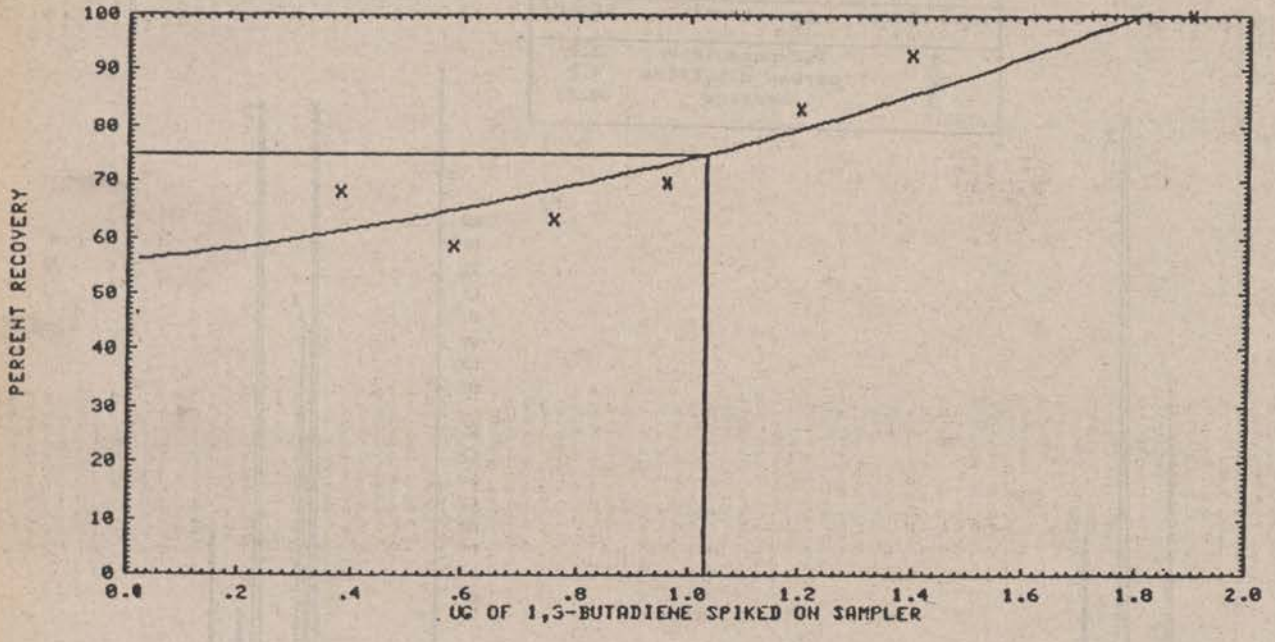

FIG. 4.2.1. THE RELIABLE QUANTITION LIMIT

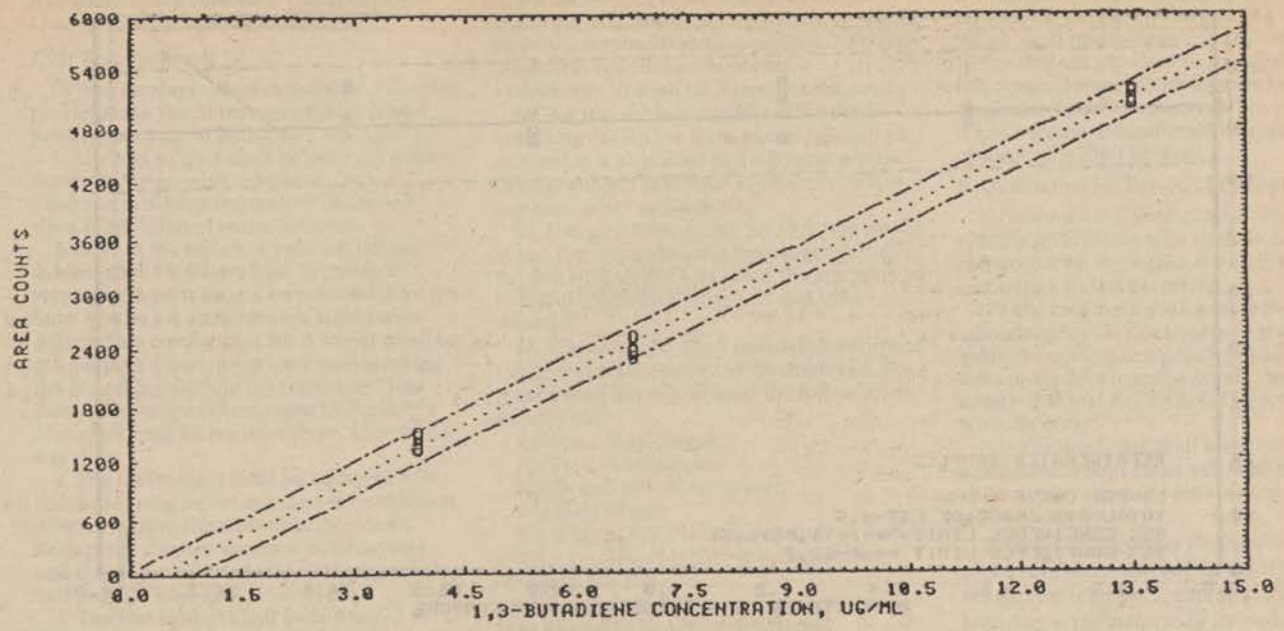

FIG. 4.3. CALIBRATION CURVE

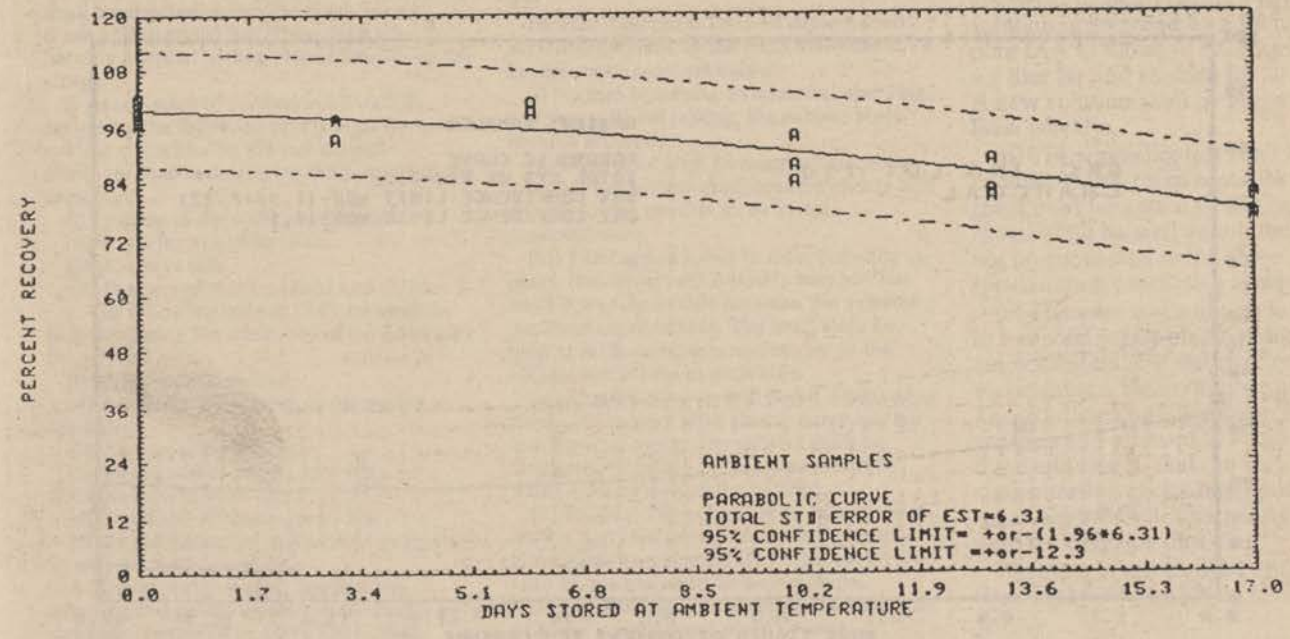

FIG. 4.6.1.1. AMBIENT TEMPERATURE STORAGE TEST

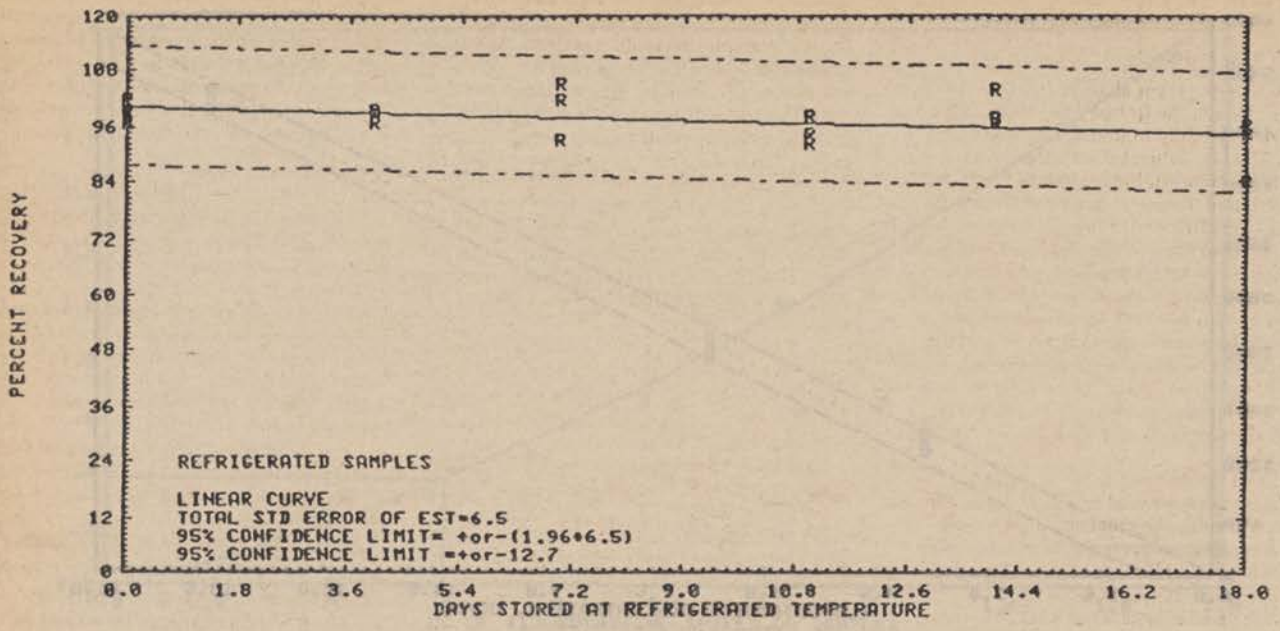

FIG. 4.6.1.2. REDUCED TEMPERATURE STORAGE TEST

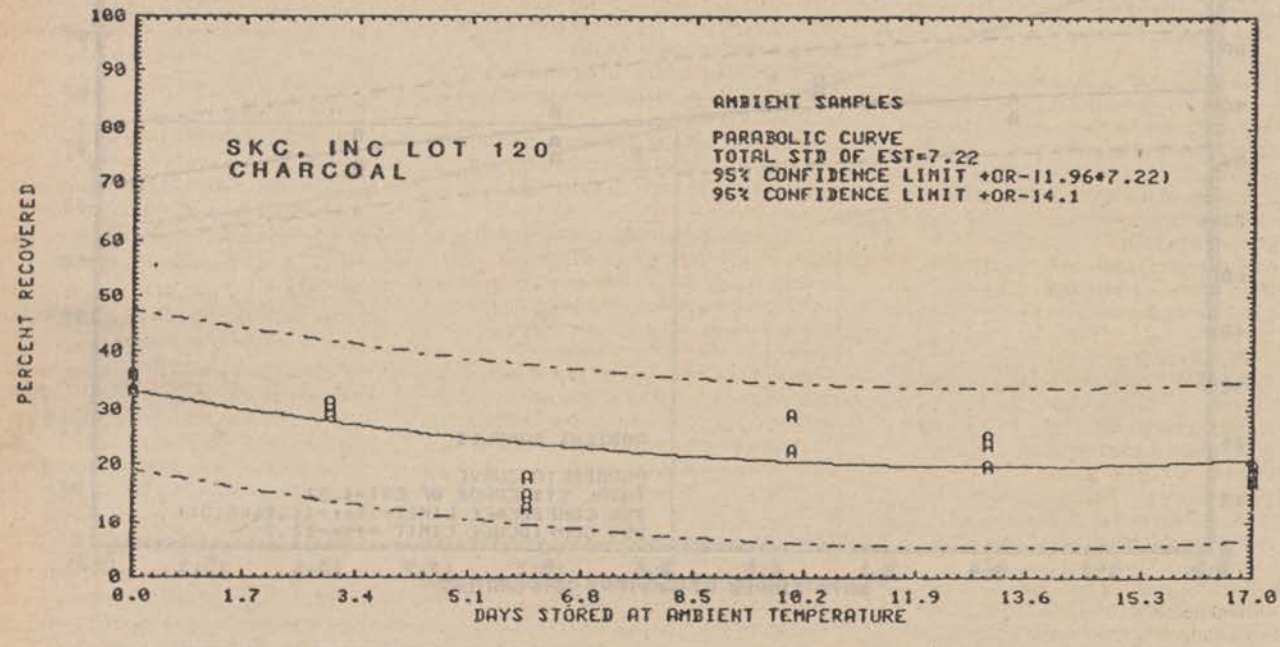

FIG. 4.6.2. AMBIENT TEMPERATURE STORAGE TEST

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Appendix E to § 1910.1015: Qualitative and Quantitative Fit Testing Procedures

I. Fit Test Protocols

A. The employer shall include the following provisions in the fit test procedures. These provisions apply to both QLFT and QNFT.

1. The test subject shall be allowed to pick the most comfortable respirator from a selection including respirators of various sizes from different manufacturers.

2. Prior to the selection process, the test subject shall be shown how to put on a respirator, how it should be positioned on the face, how to set strap tension and how to determine a comfortable fit. A mirror shall be available to assist the subject in evaluating the fit and positioning the respirator. This instruction may not constitute the subject's formal training on respirator use, as it is only a review.

3. The test subject shall be informed that he/she is being asked to select the respirator which provides the most comfortable fit. Each respirator represents a different size and shape, and if fitted and used properly, will provide adequate protection.

4. The test subject shall be instructed to hold each facepiece up to the face and eliminate those which obviously do not give a comfortable fit.

5. The more comfortable facepieces are noted; the most comfortable mask is donned and worn at least five minutes to assess comfort. Assistance in assessing comfort can be given by discussing the points in item 6 below. If the test subject is not familiar with using a particular respirator, the test subject shall be directed to don the mask several times and to adjust the straps each time to become adept at setting proper tension on the straps.

6. Assessment of comfort shall include reviewing the following points with the test subject and allowing the test subject adequate time to determine the comfort of the respirator:

(i) Position of the mask on the nose;

(ii) Room for eye protection;

(iii) Room to talk;

(iv) Position of mask on face and cheeks.

7. The following criteria shall be used to help determine the adequacy of the respirator fit:

(i) Chin properly placed;

(ii) Adequate strap tension, not overly tightened;

(iii) Fit across nose bridge;

(iv) Respirator of proper size to span distance from nose to chin;

(v) Tendency of respirator to slip;

(vi) Self-observation in mirror to evaluate fit and respirator position.

8. The test subject shall conduct the negative and positive pressure fit checks as described below or in ANSI Z88.2–1980. Before conducting the negative or positive pressure test, the subject shall be told to seat the mask on the face by moving the head from side-to-side and up and down slowly while taking in a few slow deep breaths. Another facepiece shall be selected and retested if the test subject fails the fit check tests.

9. The test shall not be conducted if there is any hair growth between the skin and the facepiece sealing surface, such as stubble beard growth, beard, or long sideburns which cross the respirator sealing surface. Any type of apparel which interferes with a satisfactory fit shall be altered or removed.

10. If a test subject exhibits difficulty in breathing during the tests, she or he shall be referred to a physician to determine whether the test subject can wear a respirator while performing her or his duties.

11. If at any time within the first two weeks of use the respirator becomes uncomfortable, the test subject shall be given the opportunity to select a different facepiece and to be retested.

12. The employer shall maintain a record of the fit test administered to an employee. The record shall contain at least the following information:

(i) Name of employee;

(ii) Type of respirator;

(iii) Brand, size of respirator;

(iv) Date of test;

(v) Where QNFT is used: the fit factor, strip chart recording or other recording of the results of the test.

The record shall be maintained until the next annual fit test is administered.

13. Exercise regimen. Prior to the commencement of the fit test, the test subject shall be given a description of the fit test and the test subject's responsibilities during the test procedure. The description of the process shall include a description of the test exercises that the subject will be performing. The respirator to be tested shall be worn for at least 5 minutes before the start of the fit test.

14. Test Exercises. The test subject shall perform exercises, in the test environment, in the manner described below:

(i) Normal breathing. In a normal standing position, without talking, the subject shall breathe normally.

(ii) Deep breathing. In a normal standing position, the subject shall breathe slowly and deeply, taking caution so as to not hyperventilate.

(iii) Turning head side to side. Standing in place, the subject shall slowly turn his/her head from side to side between the extreme positions on each side. The head shall be held at each extreme momentarily so the subject can inhale at each side.

(iv) Moving head up and down. Standing in place, the subject shall slowly move his/her head up and down. The subject shall be instructed to inhale in the up position (i.e., when looking toward the ceiling).

(v) Talking. The subject shall talk out loud slowly and loud enough so as to be heard clearly by the test conductor. The subject can read from a prepared text such as the Rainbow Passage, count backward from 100, or recite a memorized poem or song.

(vi) Grimace. The test subject shall grimace by smiling or frowning.

(vii) Bending over. The test subject shall bend at the waist as if he/she were to touch his/her toes. Jogging in place shall be substituted for this exercise in those test environments such as shroud type QNFT units which prohibit bending at the waist.

(viii) Normal breathing. Same as exercise (i).

Each test exercise shall be performed for one minute except for the grimace exercise which shall be performed for 15 seconds.

The test subject shall be questioned by the test conductor regarding the comfort of the respirator upon completion of the protocol. If it has become uncomfortable, another model of respirator shall be tried.

B. Qualitative Fit Test (QLFT) Protocols

1. *General.* (i) The employer shall assign specific individuals who shall assume full responsibility for implementing the respirator qualitative fit test program.

(ii) The employer shall ensure that persons administering QLFT are able to prepare test solutions, calibrate equipment and perform tests properly, recognize invalid tests, and assure that test equipment is in proper working order.

(iii) The employer shall assure that QLFT equipment is kept clean and well maintained so as to operate at the parameters for which it was designed.

2. *Isoamyl Acetate Protocol.*—(i) *Odor threshold screening.* The odor threshold screening test, performed without wearing a respirator, is intended to determine if the individual tested can detect the odor of isoamyl acetate.

(a) Three 1 liter glass jars with metal lids are required.

(b) Odor free water (e.g. distilled or spring water) at approximately 25 °C shall be used for the solutions.

(c) The isoamyl acetate (IAA) (also known at isopentyl acetate) stock solution is prepared by adding 1 cc of pure IAA to 800 cc of odor free water in a 1 liter jar and shaking for 30 seconds. A new solution shall be prepared at least weekly.

(d) The screening test shall be conducted in a room separate from the room used for actual fit testing. The two rooms shall be well ventilated but shall not be connected to the same recirculating ventilation system.

(e) The odor test solution is prepared in a second jar by placing 0.4 cc of the stock solution into 500 cc of odor free water using a clean dropper or pipette. The solution shall be shaken for 30 seconds and allowed to stand for two to three minutes so that the IAA concentration above the liquid may reach equilibrium. This solution shall be used for only one day.

(f) A test blank shall be prepared in a third jar by adding 500 cc of odor free water.

(g) The odor test and test blank jars shall be labeled 1 and 2 for jar identification. Labels shall be placed on the lids so they can be periodically peeled, dried off and switched to maintain the integrity of the test.

(h) The following instruction shall be typed on a card and placed on the table in front of the two test jars (i.e., 1 and 2):

"The purpose of this test is to determine if you can smell banana oil at a low concentration. The two bottles in front of you contain water. One of these bottles also contains a small amount of banana oil. Be sure the covers are on tight, then shake each bottle for two seconds. Unscrew the lid of each bottle, one at a time, and sniff at the mouth of the bottle. Indicate to the test conductor which bottle contains banana oil."

(i) The mixtures used in the IAA odor detection test shall be prepared in an area separate from where the test is performed, in order to prevent olfactory fatigue in the subject.

(j) If the test subject is unable to correctly identify the jar containing the odor test solution, the IAA qualitative fit test shall not be performed.

(k) If the test subject correctly identifies the jar containing the odor test solution, the test subject may proceed to respirator selection and fit testing.

(ii) *Isoamyl acetate fit test.* (a) The fit test chamber shall be similar to a clear 55-gallon drum liner suspended inverted over a 2-foot diameter frame so that the top of the chamber is about 6 inches above the test subject's head. The inside top center of the chamber shall have a small hook attached.

(b) Each respirator used for the fitting and fit testing shall be equipped with organic vapor cartridges or offer protection against organic vapors. The cartridges or masks shall be changed at least weekly.

(c) After selecting, donning, and properly adjusting a respirator, the test subject shall wear it to the fit testing room. This room shall be separate from the room used for odor threshold screening and respirator selection, and shall be well ventilated, as by an exhaust fan or lab hood, to prevent general room contamination.

(d) A copy of the test exercises and any prepared text from which the subject is to read shall be taped to the inside of the test chamber.

(e) Upon entering the test chamber, the test subject shall be given a 6-inch by 5-inch piece of paper towel, or other porous, absorbent, single-ply material, folded in half and wetted with 0.75 cc of pure IAA. The test subject shall hang the wet towel on the hook at the top of the chamber.

(f) Allow two minutes for the IAA test concentration to stabilize before starting the fit test exercises. This would be an appropriate time to talk with the test subject; to explain the fit test, the importance of his/her cooperation, and the purpose for the head exercises; or to demonstrate some of the exercises.

(g) If at any time during the test, the subject detects the banana like odor of IAA, the test has failed. The subject shall quickly exit from the test chamber and leave the test area to avoid olfactory fatigue.

(h) If the test has failed, the subject shall return to the selection room and remove the respirator, repeat the odor sensitivity test, select and put on another respirator, return to the test chamber and again begin the procedure described in (a) through (g) above. The process continues until a respirator that fits well has been found. Should the odor sensitivity test be failed, the subject shall wait about 5 minutes before retesting. Odor sensitivity will usually have returned by this time.

(i) When a respirator is found that passes the test, its efficiency shall be demonstrated for the subject by having the subject break the face seal and take a breath before exiting the chamber.

(j) When the test subject leaves the chamber, the subject shall remove the saturated towel and return it to the person conducting the test. To keep the test area from becoming contaminated, the used towels shall be kept in a self sealing bag so there is no significant IAA concentration build-up in the test chamber during subsequent tests.

3. *Saccharin Solution Aerosol Protocol.* The saccharin solution aerosol QLFT protocol is the only currently available, validated test protocol for use with particulate disposable dust respirators not equipped with high-efficiency filters. The entire screening and testing procedure shall be explained to the test subject prior to the conduct of the screening test.

(i) Taste threshold screening. The saccharin taste threshold screening, performed without wearing a respirator, is intended to determine whether the individual being tested can detect the taste of saccharin.

(a) During threshold screening as well as during fit testing, subjects shall wear an enclosure about the head and shoulders that is approximately 12 inches in diameter by 14 inches tall with at least the front portion clear and that allows free movements of the head when a respirator is worn. An enclosure substantially similar to the 3M hood assembly, parts # FT 14 and # FT 15 combined, is adequate.

(b) The test enclosure shall have a 3/4-inch hole in front of the test subject's nose and mouth area to accommodate the nebulizer nozzle.

(c) The test subject shall don the test enclosure. Throughout the threshold screening test, the test subject shall breathe through his/her wide open mouth with tongue extended.

(d) Using a DeVilbiss Model 40 Inhalation Medication Nebulizer the test conductor shall spray the threshold check solution into the enclosure. This nebulizer shall be clearly marked to distinguish it from the fit test solution nebulizer.

(e) The threshold check solution consists of 0.83 grams of sodium saccharin USP in 1 cc of warm water. It can be prepared by putting 1 cc of the fit test solution (see (ii)(e) below) in 100 cc of distilled water.

(f) To produce the aerosol, the nebulizer bulb is firmly squeezed so that it collapses completely, then released and allowed to fully expand.

(g) Ten squeezes are repeated rapidly and then the test subject is asked whether the saccharin can be tasted.

(h) If the first response is negative, ten more squeezes are repeated rapidly and the test subject is again asked whether the saccharin is tasted.

(i) If the second response is negative, ten more squeezes are repeated rapidly and the test subject is again asked whether the saccharin is tasted.

(j) The test conductor will take note of the number of squeezes required to solicit a taste response.

(k) If the saccharin is not tasted after 30 squeezes (step 10), the test subject may not perform the saccharin fit test.

(l) If a taste response is elicited, the test subject shall be asked to take note of the taste for reference in the fit test.

(m) Correct use of the nebulizer means that approximately 1 cc of liquid is used at a time in the nebulizer body.

(n) The nebulizer shall be thoroughly rinsed in water, shaken dry, and refilled at least each morning and afternoon or at least every four hours.

(ii) Saccharin solution aerosol fit test procedure. (a) The test subject may not eat, drink (except plain water), or chew gum for 15 minutes before the test.

(b) The fit test uses the same enclosure described in (i) above.

(c) The test subject shall don the enclosure while wearing the respirator selected in section (i) above. The respirator shall be properly adjusted and equipped with a particulate filter(s).

(d) A second DeVilbiss Model 40 Inhalation Medication Nebulizer is used to spray the fit test solution into the enclosure. This nebulizer shall be clearly marked to distinguish it from the screening test solution nebulizer.

(e) The fit test solution is prepared by adding 83 grams of sodium saccharin to 100 cc of warm water.

(f) As before, the test subject shall breathe through the wide open mouth with tongue extended.

(g) The nebulizer is inserted into the hole in the front of the enclosure and the fit test solution is sprayed into the enclosure using the same number of squeezes required to elicit a taste response in the screening test.

(h) After generating the aerosol the test subject shall be instructed to perform the exercises in section I. A. 14 above.

(i) Every 30 seconds the aerosol concentration shall be replenished using one half the number of squeezes as initially.

(j) The test subject shall indicate to the test conductor if at any time during the fit test the taste of saccharin is detected.

(k) If the taste of saccharin is detected, the fit is deemed unsatisfactory and a different respirator shall be tried.

4. *Irritant Fume Protocol.* (i) The respirator to be tested shall be equipped with high-efficiency particulate air (HEPA) filters.

(ii) The test subject shall be allowed to smell a weak concentration of the irritant smoke before the respirator is donned to become familiar with its characteristic odor.

(iii) Break both ends of a ventilation smoke tube containing stannic oxychloride, such as the MSA part No. 5645, or equivalent. Attach one end of the smoke tube to a low flow air pump set to deliver 200 milliliters per minute.

(iv) Advise the test subject that the smoke can be irritating to the eyes and instruct the subject to keep his/her eyes closed while the test is performed.

(v) The test conductor shall direct the stream of irritant smoke from the smoke tube towards the face seal area of the test subject. He/She shall begin at least 12 inches from the facepiece and gradually move to within one inch, moving around the whole perimeter of the mask.

(vi) The exercises identified in section I. A. l4 above shall be performed by the test subject while the respirator seal is being challenged by the smoke.

(vii) Each test subject passing the smoke test without evidence of a response shall be given a sensitivity check of the smoke from the same tube once the respirator has been removed to determine whether he/she reacts to the smoke. Failure to evoke a response shall void the fit test.

(viii) The fit test shall be performed in a location with exhaust ventilation sufficient to prevent general contamination of the testing area by the test agent.

C. Quantitative Fit Test (QNFT) Protocol

1. *General.* (i) The employer shall assign specific individuals who shall assume full responsibility for implementing the respirator quantitative fit test program.

(ii) The employer shall ensure that persons administering QNFT are able to calibrate equipment and perform tests properly, recognize invalid tests, calculate fit factors properly and assure that test equipment is in proper working order.

(iii) The employer shall assure that QNFT equipment is kept clean and well maintained so as to operate at the parameters for which it was designed.

2. *Definitions.* (i) Quantitative fit test. The test is performed in a test chamber. The normal air-purifying element of the respirator is replaced by a high-efficiency particulate air (HEPA) filter in the case of particulate QNFT aerosols or a sorbent offering contaminant penetration protection equivalent to high-efficiency filters where the QNFT test agent is a gas or vapor.

(ii) Challenge agent means the aerosol, gas or vapor introduced into a test chamber so that its concentration inside and outside the respirator may be measured.

(iii) Test subject means the person wearing the respirator for quantitative fit testing.

(iv) Normal standing position means standing erect and straight with arms down along the sides and looking straight ahead.

(v) Maximum peak penetration method means the method of determining test agent penetration in the respirator as determined by strip chart recordings of the test. The highest peak penetration for a given exercise is taken to be representative of average penetration into the respirator for that exercise.

(vi) Average peak penetration method means the method of determining test agent penetration into the respirator utilizing a strip chart recorder, integrator, or computer. The agent penetration is determined by an average of the peak heights on the graph or by computer integration, for each exercise except the grimace exercise. Integrators or computers which calculate the actual test agent penetration into the respirator for each exercise will also be considered to meet the requirements of the average peak penetration method.

3. *Apparatus.*—(i) *Instrumentation.* Aerosol generation, dilution, and measurement systems using corn oil or sodium chloride as test aerosols shall be used for quantitative fit testing.

(ii) *Test chamber.* The test chamber shall be large enough to permit all test subjects to perform freely all required exercises without disturbing the challenge agent concentration or the measurement apparatus. The test chamber shall be equipped and constructed so that the challenge agent is effectively isolated from the ambient air, yet uniform in concentration throughout the chamber.

(iii) When testing air-purifying respirators, the normal filter or cartridge element shall be replaced with a high-efficiency particulate filter supplied by the same manufacturer.

(iv) The sampling instrument shall be selected so that a strip chart record may be made of the test showing the rise and fall of the challenge agent concentration with each inspiration and expiration at fit factors of at least 2,000. Integrators or computers which integrate the amount of test agent penetration leakage into the respirator for each exercise may be used provided a record of the readings is made.

(v) The combination of substitute air-purifying elements, challenge agent and challenge agent concentration in the test chamber shall be such that the test subject is not exposed in excess of an established exposure limit for the challenge agent at any time during the testing process.

(vi) The sampling port on the test specimen respirator shall be placed and constructed so that no leakage occurs around the port (e.g. where the respirator is probed), a free air flow is allowed into the sampling line at all times and so that there is no interference with the fit or performance of the respirator.

(vii) The test chamber and test set up shall permit the person administering the test to observe the test subject inside the chamber during the test.

(viii) The equipment generating the challenge atmosphere shall maintain the concentration of challenge agent inside the test chamber constant to within a 10 percent variation for the duration of the test.

(ix) The time lag (interval between an event and the recording of the event on the strip chart or computer or integrator) shall be kept to a minimum. There shall be a clear association between the occurrence of an event inside the test chamber and its being recorded.

(x) The sampling line tubing for the test chamber atmosphere and for the respirator sampling port shall be of equal diameter and of the same material. The length of the two lines shall be equal.

(xi) The exhaust flow from the test chamber shall pass through a high-efficiency filter before release.

(xii) When sodium chloride aerosol is used, the relative humidity inside the test chamber shall not exceed 50 percent.

(xiii) The limitations of instrument detection shall be taken into account when determining the fit factor.

(xiv) Test respirators shall be maintained in proper working order and inspected for deficiencies such as cracks, missing valves and gaskets, etc.

4. *Procedural Requirements.* (i) When performing the initial positive or negative pressure test the sampling line shall be crimped closed in order to avoid air pressure leakage during either of these tests.

(ii) An abbreviated screening isoamyl acetate test or irritant fume test may be utilized in order to quickly identify poor fitting respirators which passed the positive and/or negative pressure test and thus reduce the amount of QNFT time. When performing a screening isoamyl acetate test, combination high-efficiency organic vapor cartridges/canisters shall be used.

(iii) A reasonably stable challenge agent concentration shall be measured in the test chamber prior to testing. For canopy or shower curtain type of test units the determination of the challenge agent stability may be established after the test subject has entered the test environment.

(iv) Immediately after the subject enters the test chamber, the challenge agent concentration inside the respirator shall be measured to ensure that the peak penetration does not exceed 5 percent for a half mask or l percent for a full facepiece respirator.

(v) A stable challenge concentration shall be obtained prior to the actual start of testing.

(vi) Respirator restraining straps shall not be overtightened for testing. The straps shall be adjusted by the wearer without assistance from other persons to give a reasonably comfortable fit typical of normal use.

(vii) The test shall be terminated whenever any single peak penetration exceeds 5 percent for half masks and 1 percent for full facepiece respirators. The test subject shall be refitted and retested. If two of the three required tests are terminated, the fit shall be deemed inadequate.

(viii) In order to successfully complete a QNFT, three successful fit tests are required. The results of each of the three independent fit tests must exceed the minimum fit factor needed for the class of respirator (e.g. quarter facepiece respirator, half mask respirator, full facepiece respirator) as specified in section (g) of the standard.

(ix) Calculation of fit factors.

(a) The fit factor shall be determined for the quantitative fit test by taking the ratio of the average chamber concentration to the concentration measured inside the respirator for each test exercise except the grimace exercise.

(b) The average test chamber concentration is the arithmetic average of the test chamber

concentration at the beginning and of the end of the test.

(c) The concentration of the challenge agent inside the respirator shall be determined by one of the following methods:

(*1*) Average peak concentration

(*2*) Maximum peak concentration

(*3*) Integration by calculation of the area under the individual peak for each exercise except the grimace exercise. This includes computerized integration.

(x) Interpretation of test results. The fit factor established by the quantitative fit testing shall be the lowest of the three fit factor values calculated from the three required fit tests.

(xi) The test subject shall not be permitted to wear a half mask, quarter facepiece, or full facepiece respirator unless a minimum fit factor of 100 is obtained.

(xii) Filters used for quantitative fit testing shall be replaced at least weekly or whenever increased breathing resistance is encountered, or when the test agent has altered the integrity of the filter media. Organic vapor cartridges/canisters shall be replaced daily (when used) or sooner if there is any indication of breakthrough by a test agent.

II. Facepiece Seal Fit Checks—Recommended Procedures

A. *Positive pressure fit check.* Close off the exhalation valve and exhale gently into the facepiece. The face fit is considered satisfactory if a slight positive pressure can be built up inside the facepiece without any evidence of outward leakage of air at the seal. For most respirators this method of leak testing requires the wearer to first remove the exhalation valve cover before closing off the exhalation valve and then carefully replacing it after the test.

B. *Negative pressure fit check.* Close off the inlet opening of the canister or cartridge(s) by covering with the palm of the hand(s) or by replacing the filter seal(s), inhale gently so that the facepiece collapses slightly, and hold the breath for ten seconds. If the facepiece remains in its slightly collapsed condition and no inward leakage of air is detected, the tightness of the respirator is considered satisfactory.

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August 10, 1990

Part III

Federal Reserve System

12 CFR Parts 208 and 225

Capital Adequacy Guidelines; Minimum Tier 1 Leverage Measure and Transition Capital Standards; Final Rule

FEDERAL RESERVE SYSTEM

12 CFR Parts 208 and 225

[Regulation H, Regulation Y; Docket No. R-0683]

Capital Adequacy Guidelines; Minimum Tier 1 Leverage Measure and Transition Capital Standards

AGENCY: Board of Governors of the Federal Reserve System.

ACTION: Final rule.

SUMMARY: On December 29, 1989, the Board proposed for public comment transition capital guidelines to be applied through the end of 1990, as well as guidelines for a new capital to total assets leverage ratio. The Board is now issuing in final form transition capital standards and capital leverage guidelines that are substantially similar to those proposed. The standards the Board is adopting are minimum requirements. Any institution experiencing or anticipating significant growth would be expected to maintain capital ratios, including tangible capital positions, well above the minimum levels. In all cases, banking institutions should hold capital commensurate with the level and nature of all of the risks, including the volume and severity of problem loans, to which they are exposed.

EFFECTIVE DATE: September 10, 1990.

FOR FURTHER INFORMATION CONTACT: Richard Spillenkothen, Deputy Associate Director (202/452–2594), Roger T. Cole, Assistant Director (202/452–2618), Rhoger H. Pugh, Manager (202/728–5883), or Kelly S. Shaw, Senior Financial Analyst (202/452–3054), Division of Banking Supervision and Regulation, Board of Governors; Michael J. O'Rourke, Senior Attorney (202/452–3288) or Mark J. Tenhundfeld, Attorney (202/452–3612), Legal Division, Board of Governors; or Donald E. Schmid, Manager (212/720–6611) or Manuel J. Schnaidman, Senior Financial Analyst (212/720–6710), Federal Reserve Bank of New York. For the hearing impaired *only*, Telecommunication Device for the Deaf (TDD), Earnestine Hill or Dorothea Thompson (202/452–3544).

SUPPLEMENTARY INFORMATION:

I. Overview and Summary

When the Board of Governors of the Federal Reserve System ("Board") issued final risk-based capital guidelines on January 19, 1989, it indicated that the existing 5.5 percent and 6 percent primary and total capital to total assets (leverage) ratios would stay in effect at least until the end of 1990, when the interim minimum risk-based capital ratios take effect. The Board also indicated that it would consider proposing a revised leverage constraint that, if adopted, would replace the existing leverage guidelines. It was contemplated that the definition of capital for the new leverage guidelines would be consistent with the risk-based capital definition.

On December 29, 1989, the Board proposed for public comment transition capital guidelines to be applied through the end of 1990, as well as guidelines for a new leverage constraint. The comment period for the Federal Reserve's proposal ended on March 9, 1990. The Board received comments addressing various aspects of the proposal from 45 public commenters.

Based upon the comments received, and further consideration of the issues involved, the Board is now issuing in final form transition capital standards and capital leverage guidelines that are substantially similar to those proposed. The Board believes that adoption of these standards and guidelines should assist state-chartered member banks and bank holding companies (collectively, "banking organizations") in formulating their capital planning process and in strengthening their capital base.

Under the transition capital standards, a banking organization may choose up to the end of 1990 to conform to either the existing minimum capital adequacy ratios (5.5 percent primary capital and 6 percent total capital to total assets) or to the 7.25 percent year-end 1990 risk-based capital standard. The board is also establishing and applying during this period a minimum ratio of 3 percent Tier 1 capital to total assets (leverage ratio). For leverage purposes, Tier 1 is defined consistent with the year-end 1992 risk-based capital guidelines.

The existing 5.5 percent primary and 6.0 percent total capital to total assets leverage ratios will be dropped after year-end 1990. The new Tier 1 leverage ratio will then constitute the minimum capital to total assets standard for banking organizations.

The standards the Board is adopting are minimum requirements. Any institution operating at or near these levels would be expected to have well-diversified risk, including no undue interest rate risk exposure, excellent asset quality, high liquidity, good earnings and, in general, would have to be considered a strong banking organization, rated composite 1 under the appropriate bank or bank holding company rating system. Any institutions experiencing or anticipating significant growth would be expected to maintain capital ratios, including tangible capital positions, well above the minimum levels as has been the case in the past. For example, most such banking organizations generally have operated at capital levels ranging from 100 to 200 basis points above the stated minimums. Higher capital ratios could be required if warranted by the particular circumstances or risk profiles of individual banking organizations. Thus, for all but the most highly-rated institutions meeting the conditions set forth above, the minimum Tier 1 leverage ratio is to be 3 percent plus an additional cushion of at least 100 to 200 basis points. In all cases, banking institutions should hold capital commensurate with the level and nature of all of the risks, including the volume and severity of problem loans, to which they are exposed.

Whenever appropriate, including when an organization is undertaking expansion, seeking to engage in new activities or otherwise facing unusual or abnormal risks, the Board will continue to consider the level of an organization's tangible Tier 1 leverage ratio (after deducting all intangibles) in making an overall assessment of capital adequacy. This is consistent with the Federal Reserve's risk-based capital guidelines and long-standing Board policy and practice under the current leverage guidelines. Organizations experiencing growth, whether internally or by acquisition, are expected to maintain strong capital positions substantially above minimum supervisory levels, without significant reliance on intangible assets.

II. Background

The Federal Reserve's risk-based capital guidelines adopted in January 1989 set forth an interim minimum risk-based ratio effective year-end 1990 and a final minimum risk-based standard effective year-end 1992. In issuing its risk-based capital guidelines, the Board indicated that the existing 5.5 and 6.0 percent primary and total capital to total assets (leverage) ratios would stay in effect, at least until the end of 1990. A principal reason for this was to retain a capital constraint until the interim minimum risk-based capital ratios take effect.

The Board also indicated that even after minimum risk-based capital ratios become effective, retention of an overall leverage constraint might be deemed appropriate because the risk-based capital framework does not incorporate a comprehensive measure of interest rate risk. A minimun ratio of capital to

total assets would help to address this potential problem by imposing an overall limitation on the extent to which a banking organization could leverage its equity capital base.

In addition to interest rate risk, capital ratios may also not take full or explicit account of certain other risk factors that can affect a banking organization's risk profile. These factors include funding and market risks; investment or loan portfolio concentrations; asset quality; and the adequacy of internal policies, systems, and controls. These factors, which must be taken into account in determining the overall risk profile and capital adequacy of a banking organization, also suggest the need to encourage banking organizations to operate well above minimum supervisory ratios.

In issuing its risk-based capital guidelines, the Board indicated that retention of the existing leverage ratios would provide an element of stability during the risk-based capital transition period. The Board further stated that if retention of an overall leverage standard were deemed appropriate in the long-run, the Federal Reserve would consider replacing the existing primary and total capital to total assets leverage ratios with a standard that incorporates a definition of capital that is consistent with the definitions contained in the risk-based capital framework. At the time, the Board indicated that a leverage standard based upon a revised definition of capital, and used in conjunction with a strong risk-based capital requirement, could be set at a level different from the existing leverage standard it would replace.

On December 29, 1989, the Board accordingly proposed for public comment transition capital standards to be applied to state member banks and bank holding companies through the end of 1990, as well as guidelines for a new leverage constraint to be applied to banking organizations, which, if adopted, would replace the existing leverage guidelines. The comment period for the proposal ended March 9, 1990. The Board received comments from 45 public respondents that addressed various aspects of the proposal.[1]

Over 80 percent of the 39 respondents that addressed the proposed leverage guidelines supported the concept of a leverage constraint, although a number had reservations on particular details of the Board's proposed leverage guidelines. Among the issues commenters raised in connection with the leverage constraint was its relationship to banking organizations' CAMEL/BOPEC ratings, the primacy of the risk-based measure, and the definition of capital.

Only nine commenters discussed the Board's proposed transition capital standards. All agreed that the proposal to permit banking organizations a choice of conforming to either the existing minimum capital adequacy ratios or the 7.25 percent year-end 1990 risk-based capital standard would be beneficial.

Based on the comments received and further consideration of the issues involved, the Board is now issuing in final form transition capital guidelines to be applied through the end of 1990, as well as guidelines for a new minimum capital to total assets ratio which will replace the existing leverage guidelines at the end of 1990. These guidelines are substantially similar to those proposed. Taken together, the standards the Board is adopting should assist banking organizations in their capital planning process and, where necessary, their efforts to raise additional capital and strengthen their capital base.

III. Transition and Leverage Standards

A. Transition Standards

The Board proposed transition capital standards to apply during the first phase of the risk-based capital transition period, which ends at year-end 1990. All respondents that commented on this issue endorsed the standards. Accordingly, the Board is issuing the transition capital standards in the form proposed.

Under the adopted transition capital standards, a banking organization may conform to either the existing minimum capital adequacy ratios of 5.5 percent primary capital and 6 percent total capital to total assets, *or* to the 7.25 percent year-end 1990 minimum risk-based capital standard. It should be emphasized that banking organizations are not required to meet the interim risk-based standard prior to its year-end 1990 effective date. Rather, organizations have the option of complying with the risk-based standard during 1990, in lieu of meeting the existing primary and total capital adequacy guidelines. Regardless of which of these options is chosen during this period banking organizations would also have to meet the new proposed leverage standard set forth below.

B. New Leverage Standard

The Board also proposed to establish and apply during 1990 and thereafter a minimum Tier 1 capital to total assets (leverage) ratio of 3 percent. The 3 percent Tier 1 to total assets ratio would be a minimum for the top-rated banking organizations without any supervisory, financial or operational weaknesses or deficiencies. Other organizations would be expected to maintain capital ratios of at least 100 to 200 basis points above the minimum depending on their financial condition. The Board also proposed that at the end of 1990, the Tier 1 leverage ratio would replace the existing 5.5 percent and 6.0 percent primary and total capital to total assets leverage ratios.

The vast majority of commenters, while supporting the use of a leverage constraint, expressed the view that the risk-based capital ratio should serve as the primary measure of an organization's capital adequacy. Commenters were divided on the issue of what would constitute an acceptable minimum level of Tier 1 capital to total assets. Some stated that any minimum over 3 percent would be unduly burdensome and undermine risk-based capital, while others expressed concern that the proposed 3 percent minimum was too low and could lead to an erosion of capital levels. A few respondents endorsed the Board's proposed approach of setting a 3 percent minimum ratio for top-rated organizations and requiring higher capital levels for other organizations because it offered flexibility and placed what they viewed as appropriate reliance on the examination process. A number of commenters, however, stated their concerns that this approach could result in an uneven or inconsistent application of capital standards across organizations and could lead to uncertainty in the capital planning process.

After reviewing the comments received and further considering the issues involved, the Board is adopting its proposal to establish a minimum Tier 1 capital to total assets ratio. This leverage constraint will be used as a supplement to the risk-based capital measure. The Board is also adopting its proposal that the minimum Tier 1 ratio only apply to top-rated organizations without any operating, financial or supervisory deficiencies. Other organizations will be expected to hold an additional capital cushion of at least 100 to 200 basis points, based on their particular circumstances and risk profiles. In the Board's view, this

[1] A summary of the comments received is contained in a memorandum distributed at the Federal Reserve's June 20, 1990 public meeting, at which the board adopted the transition capital standards and leverage guidelines.

approach strikes a reasonable balance between the need to set a floor that is not so high as to undermine the risk-based capital standard, and the need to provide for an adequate limitation on leverage.

The Board proposed that the definition of Tier 1 capital for leverage purposes be consistent with the year-end 1992 risk-based capital definition. A number of commenters endorsed the use of consistent definitions because, in their view, it would minimize confusion and simplify the capital planning process. Some commenters approved the use of Tier 1 capital in the leverage ratio specifically because it would establish an equity standard. A small minority, however, stated their preference for a definition of capital for leverage purposes that would include non-Tier 1 elements such as the allowance for loan and lease losses.

The Board is accordingly adopting its proposal that the leverage standard employ the year-end 1992 definition of Tier 1 capital, as set forth in the risk-based capital guidelines, [2] and exclude any non-Tier 1 elements from its definition of capital. Total assets is defined for this purpose as total consolidated assets (defined net of the allowance for loan and lease losses), less goodwill and, on a case-by-case basis, any other intangible assets or investments in subsidiaries that the primary regulator determines should be deducted from Tier 1 capital.

As proposed, at the end of 1990 the Board will drop the existing leverage ratios, that is, the 5.5 percent and 6.0 percent primary and total capital to total assets leverage ratios. The new Tier 1 capital to total assets ratio will then constitute the leverage standard for banking organizations, and will be used thereafter to supplement the risk-based ratio in determining the overall capital adequacy of banking organizations.

The new Tier 1 leverage ratio differs in a number of respects from the current primary and total capital ratios as defined under the Federal Reserve's existing leverage guidelines. For example, primary capital includes the allowance for loan and lease losses (without limitation), and total capital includes limited amounts of subordinated debt. Neither of these elements, both of which are deemed to be Tier 2 components under the risk-based capital framework, is included in the definition of capital for the new Tier 1 leverage ratio. Moreover, the current primary and total capital leverage standards do not contain an absolute minimum for the level of permanent shareholders' equity in relation to assets—a minimum that is established by the Tier 1 leverage standard. Thus, the new Tier 1 leverage ratio reflects the amount of core equity that is available to support unanticipated losses—a key prudential measure for determining the health of individual banking organizations. In addition to these benefits, adoption of Tier 1 for the purpose of comparing capital to total assets will have the advantage of bringing the definition of capital for leverage purposes into line with the definition of capital for risk-based capital purposes.

The Board emphasizes that in all cases, the standards set forth above are supervisory minimums. An institution operating at or near these levels is expected to have well-diversified risk, including no undue interest rate risk exposure; excellent asset quality; high liquidity; good earnings; and in general be considered a strong banking organization, rated composite 1 under the CAMEL rating system for banks or the BOPEC rating system for bank holding companies. Institutions with high or inordinate levels of risk are expected to operate well above minimum capital standards. As has been the case in the past, institutions experiencing or anticipating significant growth are also expected to maintain capital ratios, including tangible capital positions, well above the minimum levels. For example, most such banking organizations generally have operated at capital levels ranging from 100 to 200 basis points above the stated minimums. Higher capital ratios could be required if warranted by the particular circumstances or risk profiles of individual banking organizations. Thus, for all but the most highly-rated institutions meeting the conditions set forth above, the minimum Tier 1 leverage ratio is to be 3 percent plus an additional cushion of at least 100 to 200 basis points. In all cases, banking institutions should hold capital commensurate with the level and nature of all of the risks, including the volume and severity of problem loans, to which they are exposed.

Whenever appropriate, including when an organization is undertaking expansion, seeking to engage in new activities or otherwise facing unusual or abnormal risks, the Board will continue to consider the level of an organization's tangible Tier 1 leverage ratio (after deducting all intangibles) in making an overall assessment of capital adequacy. This is consistent with the Federal Reserve's risk-based capital guidelines and long-standing Board policy and practice under the current leverage guidelines. Organizations experiencing growth, whether internally or by acquisition, are expected to maintain strong capital positions substantially above minimum supervisory levels, without significant reliance on intangible assets.

IV. Regulatory Flexibility Act Analysis

The Federal Reserve Board certifies that adoption of this proposal would not have a significant economic impact on a substantial number of small business entities (in this case, small banking organizations), in accord with the spirit and purposes of the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*). In addition, consistent with current policy, these guidelines generally will not apply on a consolidated basis to bank holding companies with consolidated assets of less than $150 million. Moreover, rather than requiring all banking organizations to raise additional capital, the guidelines are directed by institutions whose capital positions are less than fully adequate in relation to their risk and leverage profiles.

List of Subjects

12 CFR Part 208

Accounting, Agricultural loan losses, Applications, Appraisals, Banks, Banking, Branches, Capital adequacy, Confidential business information, Dividend payments, Federal Reserve System, Flood insurance, Publication of reports of condition, Reporting and recordkeeping requirements, Securities, State member banks.

12 CFR Part 225

Administrative practice and procedure, Appraisals, Banks, Banking, Capital adequacy, Federal Reserve System, Holding companies, Reporting

[2] At the end of 1922, Tier 1 capital for state member banks includes common equity, minority interests in equity accounts of consolidated subsidiaries, and qualifying noncumulative perpetual preferred stock, less goodwill. It excludes any other intangible assets and investments in subsidiaries that the Federal Reserve determines should be deducted from capital for supervisory purposes. This could be done on a case-by-case basis or for certain classes of intangible assets. For bank holding companies, Tier 1 capital at the end of 1992 includes common equity, minority interests in equity accounts of consolidated subsidiaries, and qualifying perpetual preferred stock. (Perpetual preferred stock is limited to 25 percent of Tier 1 capital.) In addition, Tier 1 excludes goodwill, and other intangibles and investments in subsidiaries that the primary regulator determines should be deducted from capital. Such deductions could be done on a case-by-case basis or for certain classes of intangible assets. (This summary of Tier 1 capital definitions is purely illustrative in nature. Comprehensive Tier 1 capital definitions are set forth in Appendix A to part 208 of the Board's Regulation H for state member banks and in Appendix A to part 225 of the Board's Regulation Y for bank holding companies.)

and recordkeeping requirements, Securities, State member banks.

For the reasons set forth in this document, and pursuant to the Board's authority under section 5(b) of the Bank Holding Company Act of 1956 (12 U.S.C. 1844(b)), and section 910 of the International Lending Supervision Act of 1983 (12 U.S.C. 3909), the Board amends 12 CFR parts 208 and 225 as follows:

PART 208—MEMBERSHIP OF STATE BANKING INSTITUTIONS IN THE FEDERAL RESERVE SYSTEM

1. The authority citation for part 208 continues to read as follows:

Authority: Sections 9, 11(a), 11(c), 19, 21, 25, and 25(a) of the Federal Reserve Act, as amended (12 U.S.C. 321–338, 248(a), 248(c), 461, 481–486, 601, and 611, respectively); sections 4 and 13(j) of the Federal Deposit Insurance Act, as amended (12 U.S.C. 1814 and 1823(j), respectively); section 7(a) of the International Banking Act of 1978 (12 U.S.C. 3105); sections 907–910 of the International Lending Supervision Act of 1983 (12 U.S.C. 3906–3909); sections 2, 12(b), 12(g), 12(i), 15B(c)(5), 17, 17A, and 23 of the Securities Exchange Act of 1934 (15 U.S.C. 78b, 78*l*(b), 78*l*(g), 78*l*(i), 78o–4(c)(5), 78q, 78q–1, and 78w, respectively); section 5155 of the Revised Statutes (12 U.S.C. 36) as amended by the McFadden Act of 1927; and sections 1101–1122 of the Financial Institutions Reform, Recovery and Enforcement Act of 1989 (12 U.S.C. 3310 and 3331–3351).

2. Section 208.13 is revised to read as follows:

§ 208.13 Capital adequacy.

The standards and guidelines by which the capital adequacy of state member banks will be evaluated by the Board are set forth in appendix A to part 208 for risk-based capital purposes, and, with respect to the ratios relating capital to total assets, in appendix B to part 208 and in appendix B to the Board's Regulation Y, 12 CFR part 225.

Appendix A—[Amended]

3. Footnote 1 to "I. Overview" of appendix A to part 208 is revised to read as follows:

[1] Supervisory ratios that relate capital to total assets for state member banks are outlined in Appendix B of this Part and in appendix B to part 225 of the Federal Reserve's Regulation Y, 12 CFR Part 225.

4. The last sentence of the first paragraph to "IV. Minimum Supervisory Ratios and Standards" of appendix A to part 208 is removed; the existing second paragraph now becomes the third paragraph and remains unchanged; and a new paragraph is added immediately following the first paragraph. The new second paragraph reads as follows:

Institutions with high or inordinate levels of risk are expected to operate well above minimum capital standards. Banks experiencing or anticipating significant growth are also expected to maintain capital, including tangible capital positions, well above the minimum levels. For example, most such institutions generally have operated at capital levels ranging from 100 to 200 basis points above the stated minimums. Higher capital ratios could be required if warranted by the particular circumstances or risk profiles of individual banks. In all cases, banks should hold capital commensurate with the level and nature of all of the risks, including the volume and severity of problem loans, to which they are exposed.

5. A second paragraph is added to "IV. B. Transition Arrangements" of Appendix A to Part 208 to read as follows:

Through year-end 1990, banks have the option of complying with the minimum 7.25 percent year-end 1990 risk-based capital standard, in lieu of the minimum 5.5 percent primary and 6 percent total capital to total assets capital ratios set forth in appendix B to part 225 of the Federal Reserve's Regulation Y. In addition, as more fully set forth in appendix B to this part, banks are expected to maintain a minimum ratio of Tier 1 capital total assets during this transition period.

6. Appendix B is added to part 208 to read as set forth below.

Appendix B To Part 208: Capital Adequacy Guidelines for State Member Banks: Tier 1 Leverage Measure

I. Overview

The Board of Governors of the Federal Reserve System has adopted a minimum ratio to Tier 1 capital to total assets to assist in the assessment of the capital adequacy of state member banks.[1] The principal objective of this measure is to place a constraint on the maximum degree to which a state member bank can leverage its equity capital base. It is intended to be used as a supplement to the risk-based capital measure.

The guidelines apply to all state member banks on a consolidated basis and are to be used in the examination and supervisory process as well as in the analysis of applications acted upon by the Federal Reserve. The Board will review the guidelines from time to time and will consider the need for possible adjustments in light of any significant changes in the economy, financial markets, and banking practices.

II. The Tier 1 Leverage Ratio

The Board has established a minimum level of Tier 1 capital to total assets of 3 percent. An institution operating at or near these levels is expected to have well-diversified risk, including no undue interest rate risk exposure; excellent asset quality; high liquidity; good earnings; and in general be considered a strong banking organization, rated composite 1 under the CAMEL rating system of banks. Institutions not meeting these characteristics, as well as institutions with supervisory, financial, or operational weaknesses, are expected to operate well above minimum capital standards. Institutions experiencing or anticipating significant growth also are expected to maintain capital ratios, including tangible capital positions, well above the minimum levels. For example, most such banks generally have operated at capital levels ranging from 100 to 200 basis points above the stated minimums. Higher capital ratios could be required if warranted by the particular circumstances or risk profiles of individual banks. Thus, for all but the most highly-rated banks meeting the conditions set forth above, the minimum Tier 1 leverage ratio is to be 3 percent plus an additional cushion of at least 100 to 200 basis points. In all cases, banking institutions should hold capital commensurate with the level and nature of all risks, including the volume and severity of problem loans, to which they are exposed.

A bank's Tier 1 leverage ratio is calculated by dividing its Tier 1 capital (the numerator of the ratio) by its average total consolidated assets (the denominator of the ratio). The ratio will also be calculated using period-end assets whenever necessary, on a case-by-case basis. For the purpose of this leverage ratio, the definition of Tier 1 capital for year-end 1992 as set forth in the risk-based capital guidelines contained in appendix A of this part will be used.[2] Average total consolidated assets are defined as the quarterly average total assets (defined net of the allowance for loan and lease losses) reported on the bank's Reports of Condition and Income ("Call Report"), less goodwill and any other intangible assets and investments in subsidiaries that the Federal Reserve determines should be deducted from Tier 1 capital.[3]

Whenever appropriate, including when a bank is undertaking expansion, seeking to engage in new activities or otherwise facing unusual or abnormal risks, the Board will continue to consider the level of an individual bank's tangible Tier 1 leverage ratio (after deducting all intangibles) in making an overall assessment of capital adequacy. This is consistent with the Federal Reserve's risk-based capital guidelines and long-standing Board policy and practice with regard to leverage guidelines. Banks experiencing growth, whether internally or by acquisition, are expected to maintain strong capital positions substantially above minimum supervisory levels, without significant reliance on intangible assets.

[1] Supervisory risk-based capital ratios that relate capital to weighted risk assets for state member banks are outlined in Appendix A to this Part.

[2] At the end of 1992, Tier 1 capital for state member banks includes common equity, minority interests in equity accounts of consolidated subsidiaries, and qualifying noncumulative perpetual preferred stock, less goodwill. The Federal Reserve may exclude certain other intangibles and investments in subsidiaries as appropriate.

[3] Deductions from Tier 1 capital and other adjustments are discussed more fully in section II.B. of appendix A to this part.

PART 225—BANK HOLDING COMPANIES AND CHANGE IN BANK CONTROL

1. The authority citation for part 225 continues to read as follows:

Authority: 12 U.S.C. 1817(j)(13), 1818, 1831i, 1843(c)(8), 1844(b), 3106, 3108, 3907, 3909, 3310, and 3331–3351.

Appendix A—[Amended]

2. Footnote 1 to "I. Overview" of appendix A to part 225 is revised to read as follows:

[1] Supervisory ratios that relate capital to total assets for bank holding companies are outlined in appendices B and D of this part.

3. The last sentence of the first paragraph to "IV. Minimum Supervisory Ratios and Standards" of appendix A to part 225 is removed; the existing second paragraph now becomes the third paragraph and remains unchanged; and a new paragraph is added immediately following the first paragraph. The new second paragraph reads as follows:

Institutions with high or inordinate levels of risk are expected to operate well above minimum capital standards. Banking organizations experiencing or anticipating significant growth are also expected to maintain capital, including tangible capital positions, well above the minimum levels. For example, most such organizations generally have operated at capital levels ranging from 100 to 200 basis points above the stated minimums. Higher capital ratios could be required if warranted by the particular circumstances or risk profiles of individual banking organizations. In all cases, organizations should hold capital commensurate with the level and nature of all of the risks, including the volume and severity of problem loans, to which they are exposed.

4. A second paragraph is added to "IV. B. Transition Arrangements" of appendix A to part 225 to read as follows:

Through year-end 1990, banking organizations have the option of complying with the minimum 7.25 percent year-end 1990 risk-based capital standard, in lieu of the minimum 5.5 percent primary and 6 percent total capital to total assets ratios set forth in appendix B of this Part. In addition, as more fully set forth in appendix D to this part, banking organizations are expected to maintain a minimum ratio of Tier 1 capital to total assets during this transition period.

Appendix B—[Amended]

5. Three new sentences are added to the end of the first paragraph of appendix B to part 225 to read as follows:

* * * In this regard, the Board has determined that during the transition period through year-end 1990 for implementation of the risk-based capital guidelines contained in appendix A to this part and in appendix A to part 208, a banking organization may choose to fulfill the requirements of the guidelines relating capital to total assets contained in this Appendix in one of two manners. Until year-end 1990, a banking organization may choose to conform to either the 5.5 percent and 6 percent minimum primary and total capital standards set forth in this Appendix, or the 7.25 percent year-end 1990 minimum risk-based capital standard set forth in appendix A to this part and appendix A to part 208. Those organizations that choose to conform during this period to the 7.25 percent year-end 1990 risk-based capital standard will be deemed to be in compliance with the capital adequacy guidelines set forth in this appendix.

6. Appendix D is added to part 225 to read as set forth below.

Appendix D—Capital Adequacy Guidelines for Bank Holding Companies: Tier 1 Leverage Measure

I. Overview

The Board of Governors of the Federal Reserve System has adopted a minimum ratio of Tier 1 capital to total assets to assist in the assessment of the capital adequacy of bank holding companies ("banking organizations").[1] The principal objective of this measure is to place a constraint on the maximum degree to which a banking organization can leverage its equity capital base. It is intended to be used as a supplement to the risk-based capital measure.

The guidelines apply on a consolidated basis to bank holding companies with consolidated assets of $150 million or more. For bank holding companies with less than $150 million in consolidated assets, the guidelines will be applied on a bank-only basis unless: a) the parent bank holding company is engaged in nonbank activity involving significant leverage; [2] or b) the parent company has a significant amount of outstanding debt that is held by the general public.

The Tier 1 leverage guidelines are to be used in the inspection and supervisory process as well as in the analysis of applications acted upon by the Federal Reserve. The Board will review the guidelines from time to time and will consider the need for possible adjustments in light of any significant changes in the economy, financial markets, and banking practices.

II. The Tier 1 Leverage Ratio

The Board has established a *minimum* level of Tier 1 capital to total assets of 3 percent. A banking organization operating at or near these levels is expected to have well-diversified risk, including no undue interest rate risk exposure; excellent asset quality; high liquidity; good earnings; and in general be considered a strong banking organization, rated composite 1 under the BOPEC rating system for bank holding companies. Organizations not meeting these characteristics, as well as institutions with supervisory, financial, or operational weaknesses, are expected to operate well above minimum capital standards. Organizations experiencing or anticipating significant growth also are expected to maintain capital ratios, including tangible capital positions, well above the minimum levels. For example, most such organizations generally have operated at capital levels ranging from 100 to 200 basis points above the stated minimums. Higher capital ratios could be required if warranted by the particular circumstances or risk profiles of individual banking organizations. Thus, for all but the most highly-rated organizations meeting the conditions set forth above, the minimum Tier 1 leverage ratio is to be 3 percent plus an additional cushion of at least 100 to 200 basis points. In all cases, banking organizations should hold capital commensurate with the level and nature of all risks, including the volume and severity of problem loans, to which they are exposed.

A banking organization's Tier 1 leverage ratio is calculated by dividing its Tier 1 capital (the numerator of the ratio) by its average total consolidated assets (the denominator of the ratio). The ratio will also be calculated on the basis of period-end assets, whenever necessary on a case-by-case basis. For the purpose of this leverage ratio, the definition of Tier 1 capital for year-end 1992 as set forth in the risk-based capital guidelines contained in appendix A to this part will be used.[3] Average total consolidated assets are defined as the quarterly average total assets (defined net of the allowance for loan and lease losses) reported on the banking organization's Consolidated Financial Statements ("FR Y–9C Report"), less goodwill and any other intangible assets or investments in subsidiaries that the Federal Reserve determines should be deducted from Tier 1 capital.[4]

Whenever appropriate, including when an organization is undertaking expansion, seeking to engage in new activities or otherwise facing unusual or abnormal risks, the Board will continue to consider the level of an individual organization's tangible Tier 1 leverage ratio (after deducting all intangibles) in making an overall assessment of capital adequacy. This is consistent with the Federal Reserve's risk-based capital guidelines and long-standing Board policy and practice with regard to leverage guidelines. Organizations experiencing growth, whether internally or by acquisition, are expected to maintain strong

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[1] Supervisory risk-based capital ratios that relate capital to weighted risk assets for bank holding companies are outlined in Appendix A to this Part.

[2] A parent company that is engaged in significant off-balance sheet activities would generally be deemed to be engaged in activities that involve significant leverage.

[3] At the end of 1992, Tier 1 capital for bank holding companies includes common equity, minority interests in equity accounts of consolidated subsidiaries, and qualifying perpetual preferred stock. (Perpetual preferred stock is limited to 25 percent of Tier 1 capital.) In addition, Tier 1 excludes goodwill. The Federal Reserve may exclude certain other intangibles and investments in subsidiaries as appropriate.

[4] Deductions from Tier 1 capital and other adjustments are discussed more fully in section II.B. of Appendix A to this Part.

capital positions substantially above minimum supervisory levels, without significant reliance on intangible assets.

By the order of the Board of Governors of the Federal Reserve System, August 1, 1990.

William W. Wiles,

Secretary of the Board.

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August 10, 1990

Part IV

Department of Labor

Pension and Welfare Benefits

29 CFR Parts 2570 and 2585

Prohibited Transaction Exemption Procedures; Employee Benefit Plans; Final Regulation and Removal of Interim Final Regulation

DEPARTMENT OF LABOR

Pension and Welfare Benefits Administration

29 CFR Parts 2570 and 2585

RIN 1210-AA26

Prohibited Transaction Exemption Procedures; Employee Benefit Plans

AGENCY: Pension and Welfare Benefits Administration, Labor.

ACTION: Final regulation and removal of interim final regulation.

SUMMARY: This document contains a final regulation that describes the procedures for filing and processing applications for exemptions from the prohibited transaction provisions of the Employee Retirement Income Security Act of 1974 (ERISA), the Internal Revenue Code of 1986 (the Code), and the Federal Employees' Retirement System Act of 1986 (FERSA). At this time, the Department is also removing an interim regulation which describes the exemption procedures under FERSA because such regulation is superseded by the final regulation contained herein. The Secretary of Labor is authorized to grant exemptions from the prohibited transaction provisions of ERISA, the Code, and FERSA and to establish an exemption procedure to provide for such exemptions. The final regulation updates the description of the Department of Labor's procedures to reflect changes in the Department's exemption authority and to clarify the procedures by providing a more comprehensive description of the prohibited transaction exemption process.

EFFECTIVE DATE: This regulation is effective September 10, 1990, and applies to all exemption applications filed at any time on or after that date.

FOR FURTHER INFORMATION CONTACT: Miriam Freund, Office of Exemption Determinations, Pension and Welfare Benefits Administration, U.S. Department of Labor, Washington, DC 20210, (202) 523-8194, or Susan Rees, Plan Benefits Security Division, Office of the Solicitor, U.S. Department of Labor, Washington, DC 20210, (202) 523-9141.

SUPPLEMENTARY INFORMATION: Public reporting burden for this collection of information is estimated to average 28.5 hours per response, including the time for reviewing the instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden, to Director, Office of Information Management, U.S. Department of Labor, 200 Constitution Avenue NW., Room N-1301, Washington, DC 20210; and to the Office of Information and Regulatory Affairs, Attn: OMB Desk Officer for PWBA, Office of Management and Budget, Room 3001, Washington, DC 20503.

Section 406 of ERISA prohibits certain transactions between employee benefit plans and "parties in interest" (as defined in section 3(14) of ERISA). In addition, sections 406 and 407(a) of ERISA impose restrictions on plan investments in "employer securities" (as defined in section 407(d)(1) of ERISA) and "employer real property" (as defined in section 407(d)(2) of ERISA). Most of the transactions prohibited by section 406 of ERISA are likewise prohibited by section 4975 of the Code, which imposes an excise tax on those transactions to be paid by each "disqualified person" (defined in section 4975(e)(2) of the Code in virtually the same manner as the term "party in interest") who participates in the transactions.

Both ERISA and the Code contain various statutory exemptions from the prohibited transaction rules. In addition, section 408(a) of ERISA authorizes the Secretary of Labor to grant administrative exemptions from the restrictions of ERISA sections 406 and 407(a) while section 4975(c)(2) of the Code authorizes the Secretary of the Treasury or his delegate to grant exemptions from the prohibitions of Code section 4975(c)(1). Sections 408(a) of ERISA and 4975(c)(2) of the Code direct the Secretary of Labor and the Secretary of the Treasury, respectively, to establish procedures to carry out the purposes of these sections.

Under section 3003(b) of ERISA, the Secretary of Labor and the Secretary of the Treasury are directed to consult and coordinate with each other with respect to the establishment of rules applicable to the granting of exemptions from the prohibited transaction restrictions of ERISA and the Code. Under section 3004 of ERISA, moreover, the Secretaries are authorized to develop jointly rules appropriate for the efficient administration of ERISA. Pursuant to these provisions, the Secretaries jointly issued an exemption procedure on April 28, 1975 (ERISA Proc. 75-1, 40 FR 18471, also issued as Rev. Proc. 75-26, 1975-1 C.B. 722). Under these procedures, a person seeking an exemption under both section 408(a) of ERISA and section 4975(c)(2) of the Code was obliged to file an exemption application with the Internal Revenue Service as well as with the Department of Labor.

Reorganization Plan No. 4 of 1978 (43 FR 47713, October 17, 1978, effective on December 31, 1978), transferred the authority of the Secretary of the Treasury to issue exemptions under section 4975 of the Code, with certain enumerated exceptions, to the Secretary of Labor. As a result, the Secretary of Labor now possesses authority under section 4975(c)(2) of the Code, as well as under section 408(a) of ERISA, to issue individual and class exemptions from the prohibited transaction rules of ERISA and the Code. The Secretary has delegated this authority, along with most of his other responsibilities under ERISA, to the Assistant Secretary for Pension and Welfare Benefits. See Secretary of Labor's Order 1-87, 52 FR 13139 (April 21, 1987).

FERSA also contains prohibited transaction rules that are applicable to parties in interest with respect to the Federal Thrift Savings Fund established by FERSA, and the Secretary of Labor is directed to prescribe, by regulation, a procedure for granting administrative exemptions from certain of those prohibited transactions. See 5 U.S.C. 8477(c)(3).

On June 28, 1988, the Department published a proposed rule in the **Federal Register** (53 FR 24422) updating ERISA Procedure 75-1 to reflect the changes made by Reorganization Plan No. 4 and extending the procedure to applications for exemptions from the FERSA prohibited transaction rules. In addition, the proposed regulation codified various procedures developed by PWBA since the adoption of ERISA Proc. 75-1. Formal adoption of those procedures will facilitate review of exemption applications. These new procedures also fill in some of the gaps left in ERISA Proc. 75-1, thereby providing a more detailed description both of the steps to be taken by applicants in applying for exemptions and the steps normally taken by the Department in processing such applications. Finally, the proposed regulation modified some of the procedures described in ERISA Proc. 75-1 to better serve the needs of the administrative exemption program as demonstrated by the Department's experience with the program over the previous fourteen years. These amendments were intended to promote the prompt and fair consideration of all exemption applications.

The notice of proposed rulemaking gave interested persons an opportunity to comment on the proposal. In response, the Department received three letters of comment regarding several

aspects of the proposed regulation. The following discussion summarizes the proposed regulation and the issues raised by the commentators and explains the Department's reasons for adopting the provisions of the final regulation.

The Scope of the Regulation

As explained in the notice of proposed rulemaking, the regulation establishes new procedures to replace ERISA Proc. 75–1. These new procedures reflect changes in the Department of Labor's exemption authority effected by Reorganization Plan No. 4 of 1978. Thus, the procedures apply to all applications for exemption which the Department has authority to issue under section 408(a) of ERISA, or, as a result of Reorganization Plan No. 4, under section 4975(c)(2) of the Code. The procedures reflect current practice under which the Department generally treats any exemption application filed solely under section 408(a) of ERISA or solely under section 4975(c)(2) of the Code as an application for exemption filed under both of these sections if the application relates to a transaction prohibited under corresponding provisions of both ERISA and the Code. The grant of an exemption by the Department in such instances protects disqualified persons covered by the exemption from the excise taxes otherwise assessable under section 4975 (a) and (b) of the Code.

However, the procedures do not apply to applications for exemption reserved to the jurisdiction of the Secretary of the Treasury by Reorganization Plan No. 4. To ascertain the correct procedures for filing and processing applications for these exemptions, applicants should consult the Internal Revenue Service.

The Department has also concluded that it is appropriate to apply the procedures provided here to exemption applications filed under FERSA, as well as those filed under ERISA or the Code, as provided by proposed § 2570.30, which has been adopted without change in the final regulation. Although the prohibited transaction provisions of FERSA and the scope of the Department's exemptive authority under FERSA differ somewhat from that under ERISA and the Code, administrative exemption matters under FERSA are likely to involve many of the same issues as are presented by similar matters involving private plans. Thus, adopting uniform procedures should help assure uniform administration of the exemption programs.

Applications for Exemption under FERSA

On December 29, 1988, the Department published an interim regulation in the **Federal Register** (29 CFR part 2585, 53 FR 52688) describing the procedures for filing and processing applications for exemptions from the prohibited transaction provisions of FERSA. For such applications, the interim regulation adopted the procedures then currently followed (pursuant to ERISA Proc. 75–1) by applicants for exemptions from the prohibited transaction provisions of ERISA and the Code. The interim final regulation was effective commencing December 29, 1988 until the effective date of the final regulation contained herein for all prohibited transaction exemption applications (under ERISA, the Code, and FERSA).[1]

Section 2585.12 of the interim regulation provides that this regulation shall expire on the effective date of the revised prohibited transaction exemption procedure, published in proposed form on June 28, 1988, 53 FR 24422, and that the Department will publish a document removing these interim regulations when it adopts final regulations based on the published proposal. Accordingly, this notice of final rulemaking removes the interim regulations as of September 10, 1990, the effective date of the final regulation contained herein.

In regard to FERSA exemption applications, the Department received a comment relating to the adoption of ERISA class exemptions for FERSA purposes. This comment suggested that the final regulation clarify that the Department will follow the procedure authorized under section 8477(c)(3)(E) of FERSA, which permits the Secretary of Labor to determine that an exemption granted for any class of fiduciaries or transactions under section 408(a) of ERISA shall constitute an exemption for FERSA purposes upon publication of notice in the **Federal Register** without affording interested persons opportunities to present their views (in writing or at a hearing).

The procedure described in the preceding paragraph was not used in conjunction with the Department's adoption for FERSA purposes of a number of specific class exemptions under ERISA (i.e., Prohibited Transaction Exemptions (PTE) 75–1, 76–19, 80–26, 80–51, 82–63, and 86–128). In that instance, the Department published in the **Federal Register** both a notice of proposed adoption of class exemptions under ERISA (53 FR 38105, September 29, 1988), which invited the public to submit written comments or requests for a hearing on the proposed adoption, and also a notice of final adoption of these class exemptions (PTE T88–1, 53 FR 52838, December 29, 1988). In this regard, the Department notes that, with respect to ERISA class exemptions which may be proposed in the future and which may also be relevant under FERSA, the Department will solicit the views of the Executive Director of the Federal Retirement Thrift Investment Board in advance of the publication of the proposed exemption to determine whether such exemption should also be proposed for FERSA purposes.

Also regarding FERSA exemption applications, the Department received another comment requesting clarification that the mere existence of routine audit activity conducted by the Department pursuant to the requirements of section 8477(g) of FERSA [2] will not provide a basis for denial of, or failure to consider, an application for exemption under FERSA. It is the view of the Department that those audits conducted by the Department in carrying out its responsibilities in connection with its regular program of compliance audits under FERSA section 8477(g) would not constitute an "investigation" for purposes of §§ 2570.33(a)(2) and 2570.37(b) of the regulation [3] or an "examination" for purposes of § 2570.35(a)(7). [4] The Department would

[1] Under section 111 of the FERSA Technical Corrections Act of 1986 (Pub. L. 99–556, October 27, 1986), the Department's existing exemptions procedures were made applicable to exemption applications under FERSA until the earlier of the date of publication of final regulations adopting an exemption procedure or December 31, 1988.

[2] Section 8477(g) of FERSA requires the Secretary of Labor to establish a program to carry out audits to determine the level of compliance with the requirements of this section relating to fiduciary responsibilities and prohibited activities of fiduciaries with respect to the Thrift Savings Fund of the Federal Employees' Retirement System. The Department has interpreted section 8477(g) to mean that the Department has a continuing responsibility to audit the Thrift Savings Fund established by FERSA.

[3] These sections relate, in pertinent part, to: the Department's nonconsideration of exemption applications which are the subject of an investigation for possible violations of FERSA or which involve a party in interest who is the subject of such an investigation (§ 2570.33(a)(2)); and to the notification of the Division of Exemptions of certain investigations initiated after the filing of an exemption application (§ 2570.37(b)).

[4] This section of the regulation requires certain exemption applications to include copies of correspondence relating to investigations, examinations, litigation, or continuing controversies with specified Federal agencies.

not, however, be precluded from denying, or failing to consider, an application based on an investigation prompted by information arising as a result of such a routine audit.

Definitions

Section 2570.31 of the proposed regulation defined the following terms for purposes of the exemption procedures: affiliate, class exemption, Department, exemption transaction, individual exemption, and party in interest. No comments were received regarding these definitions which are adopted in the final regulation as proposed. However, the Department has added to this section a definition of the term "pooled fund" in response to a comment requesting that a special rule be added to the final regulation regarding information to be furnished in exemption applications relating to plans affected by an exemption transaction undertaken by a pooled investment vehicle. (This comment is discussed in more detail below.)

Who May Apply for Exemptions

Section 2570.32(a) of the proposed regulation provided that exemption proceedings may be initiated by the Department either on its own motion or upon the application of: (1) Any party in interest to a plan which is or may be a party to the exemption transaction, (2) any plan which is a party to the exemption transaction, or (3) an association or organization representing parties in interest who may be parties to an exemption transaction covering a class of parties in interest or a class of transactions.

One of the comments received recommended modifying this paragraph of the regulation to permit an exemption application to be filed by any fiduciary or prospective fiduciary with respect to plan assets under such fiduciary's management or control, regardless of whether such fiduciary either represents a specific plan with respect to the exemption application or would be a party to the exemption transaction. The commentator clarified his comment by explaining that he intended this category of applicants to cover prospective fiduciaries, such as persons creating and/or managing a new investment vehicle in which plans are expected to participate if the requested exemption is granted, but in which no plans participate at the time the exemption application is filed. The commentator noted that in the past the Department has granted individual exemptions to institutional investment managers in connection with their investment management of individual plans' investment accounts or pooled investment funds in which several unidentified plans may participate.

In the Department's view, the reference in proposed § 2570.32(a)(1) to "any party in interest to a plan who is or may be a party to the exemption transaction" includes the prospective fiduciaries mentioned by the commentator. Therefore, § 2570.32(a) is adopted in the final regulation without change.

Section 2570.32 (b) and (c) of the proposed regulation set forth simplified rules relating to representation of applicants by third parties. No comments were received regarding these paragraphs, which are adopted in the final regulation without change.

Applications the Department Will Not Ordinarily Consider

Section 2570.33(a) of the proposed regulation described the circumstances under which the Department will not ordinarily consider the merits of an exemption application. Thus, this paragraph provided that the Department will not ordinarily consider an incomplete application. In this regard, the Department emphasizes that applicants should not file exemption applications until they have compiled all the information required by § 2570.34 and, if applicable, § 2570.35, and can submit this information in an organized and comprehensive fashion together with all necessary supporting documents and statements. In addition, the proposal made it clear that the Department ordinarily will not consider applications that involve a transaction, or a party in interest with respect to such transaction, that is the subject of an ERISA enforcement action or investigation. In certain cases, however, the Department may exercise its discretion to consider exemption applications in these categories where, for example, deficiencies in the exemption application are merely technical, or where an enforcement matter is clearly unrelated to the exemption transaction.

One comment was received specifically regarding investigations, and it is discussed above under the heading "Applications for Exemption under FERSA." In addition, the Department has amended § 2570.33(a)(2) (relating to certain investigations and enforcement actions) to conform to a similar revision to § 2570.35(a)(7) (discussed below) made in response to two other comments received regarding the proposed requirement to include information in an application concerning certain investigations, examinations, litigation, or continuing controversy involving specified Federal agencies with respect to any plan or party in interest involved in the exemption transaction. The effect of these amendments is to expand the proposed regulation in order to broaden the scope of exemption applications which the Department will ordinarily consider.

No comments were received on paragraphs (b) and (c) of proposed § 2570.33, which are adopted without change in the final regulation. These paragraphs relate to the Department's written explanation to an applicant whose exemption application the Department has decided not to consider, and to applications for individual exemption relating to transaction(s) covered by a class exemption under consideration by the Department.

Exemption Application Contents—General Information

As previously noted in the proposed regulation, the Department's experience to date with the administrative exemption program suggests that the program's efficiency could be increased and applicants can receive more timely treatment of their applications for exemption if the quality of exemption applications filed were improved. In the past, applications have been incomplete, have omitted or misstated facts or legal analyses needed to justify requests for exemptive relief, and in some cases have been so poorly drafted that the details of the transactions for which exemptive relief is sought ("exemption transactions") are unclear. The time and effort required to deal with such deficient applications and to obtain accurate and complete information about exemption transactions have contributed to processing delays. Moreover, in many exemption applications, the discussion of the substantive basis for the exemption does not take adequate account of positions adopted by the Department with respect to other similar applications.

The proposed regulation attempted to address these problems in a number of ways. First, the proposal required that applicants provide more complete information in their applications about exemption transactions and about the plans and the parties in interest involved in those transactions. The Department's experience suggests that this additional information is very helpful, and often essential, for a complete understanding of the exemption transaction and of the context surrounding it, and that the omission of such additional information in exemption applications will delay

review of these applications on their merits.

For the same reason, the proposed regulation required filing with the exemption application copies of the relevant portions of documents bearing on transactions for which individual exemptions are sought. Such filing will avoid delays in the evaluation of exemption applications pending receipt of relevant documents. By filing comprehensive applications with necessary supporting documentation, applicants can do much to facilitate the Department's review of requested exemptions and to expedite the exemption process as a whole.

To further expedite the exemption process, the proposed regulation required that an applicant include with his application a statement explaining why the requested exemption satisfies requirements set forth in sections 408(a) of ERISA and 4975(c)(2) of the Code and 5 U.S.C. 8477(c)(3)(C) that an exemption be:

(1) Administratively feasible;

(2) In the interests of the plan and of its participants and beneficiaries; and

(3) Protective of the rights of the plan's participants and beneficiaries.

This requirement is not new. Under ERISA Proc. 75–1, applicants have been required to include with their applications statements explaining why a requested exemption satisfies the statutory prerequisites for an exemption. Too often, however, applicants have attempted to satisfy this requirement with generalizations and perfunctory assurances about the benefits to be reaped by plans and their participants and beneficiaries from the proposed exemption.

The Department will not seek out reasons to grant an exemption that has not been adequately justified by an applicant. Indeed, the Department considers that it is the responsibility of applicants to demonstrate clearly that exemptions they are requesting meet statutory criteria. Accordingly, under both the proposed and the final regulation, applicants are expected to review the statutory criteria for granting administrative exemptions and explain with as much specificity as possible why a requested exemption would pose no administrative problems, what benefits affected plans and their participants and beneficiaries can expect to receive from it, and what conditions would be attached to protect the rights of participants and beneficiaries of affected plans.[5]

Under ERISA Proc. 75–1, applicants have been given the option, but have not been required, to submit a draft of the proposed exemption. Both the proposed and the final regulation preserve this option. However, while not requiring the submission of a draft of the proposed exemption, the Department recommends that applicants include in their exemption applications draft language which defines the scope of the requested exemption, including the specific conditions under which the requested exemption would apply. A draft which explains the exemption requested in a clear and concise manner and focuses on what the applicant considers to be the essential features of the exemption transaction and the critical safeguards supporting the requested relief is likely to facilitate the process of review. Obviously, the degree of detail necessary to describe the proposed exemption adequately will vary depending on the complexity of the transaction and the kind of relief requested.

Section 2570.34 of the proposed regulation listed the information that is required in every exemption application, whether it be an application for individual or class exemption. In addition, the information specified in § 2570.35 of the regulation must be included in applications for individual exemptions. Some specific items of information are discussed below.

Shared Representation

Section 2570.34(a)(3) of the proposed regulation required each exemption application to disclose whether the same person will represent both the plan and the parties in interest involved in an exemption transaction in matters relating to the application. The proposal noted that such shared representation may raise questions under the exclusive purpose and prudence requirements of sections 403(c) and 404(a) of ERISA and under the prohibited transaction provisions of section 406 of ERISA and section 4975(c)(1) of the Code. No comments have been received regarding this subparagraph, which is adopted as proposed.

Third-Party Declarations

Section 2570.34(b)(5)(iii) of the proposed regulation required a declaration under penalty of perjury to accompany specialized statements from third-party experts submitted to support an exemption application, such as appraisals, analyses of market conditions, or opinions of independent fiduciaries. Specifically, the proposal required a declaration under penalty of perjury, that to the best of the expert's knowledge and belief, the representations made in the specialized statement are true and correct. This declaration was to be dated and signed by the expert who prepared the statement.

One of the comments received urged deletion of this requirement and expressed concern that it would cause additional expense to applicants because new third-party statements would be required once the appraiser, engineer, financial specialist, or other expert became aware of their intended use as part of an exemption application. The commentator advised subsequently that such experts either may be reluctant to provide any sort of attestation because of unknown liabilities which may arise by using the expert's report as part of an exemption application, or may seek an additional, and perhaps substantial, fee for furnishing an attestation due to the unknown liabilities.

In this regard, the Department notes that, with respect to any matter within the jurisdiction of any department or agency of the United States, it is a crime, punishable by a fine of up to $10,000 and/or imprisonment of up to five years, for anyone knowingly and willfully to falsify, conceal, or cover up by any trick, scheme or device a material fact; to make any false, fictitious, or fraudulent statements or representations; or to make or use any false writing or document knowing the same contains any false, fictitious, or fraudulent statement or entry (18 U.S.C. § 1001). It is the view of the Department that this provision applies to applicants for exemptions under ERISA, the Code, or FERSA, to fiduciaries (independent or otherwise) representing the plan in an exemption transaction, and to third-party experts who prepare statements or reports that such experts know will be included in exemption applications.

Nevertheless, the Department recognizes that third-party experts such as appraisers, bankers, financial analysts, and other specialized consultants usually do not function as fiduciaries with respect to a plan if such experts' authority, responsibility, or contact with respect to the plan is limited to providing an opinion which may be included in an exemption application and which will be considered by plan fiduciaries who will decide what, if any, action they will take on behalf of the plan based upon such

[5] The Department must find that the statutory criteria are satisfied before granting a prohibited transaction exemption. The legislative history of ERISA makes it clear, however, that the Department has broad discretion in determining whether or not to grant an exemption. H.R. Rep. 1280, 93 Cong., 2d Sess. 311 (1974).

opinion. The Department believes that such experts need not be held to the same degree of accountability regarding exemption applications covering transactions where a plan fiduciary has the authority and responsibility to make decisions on behalf of a plan. Thus, the Department has decided to modify proposed § 2570.34(b)(5)(iii) to provide that a statement of consent, rather than a declaration under penalty of perjury, is required from each such expert which acknowledges that his or her statement is being submitted to the Department as part of an exemption application. The Department believes that such a consent statement from a third-party expert will not require an applicant to obtain a new report from the expert because the expert's consent statement may refer to his or her previously issued report. (However, the Department may require an updated report in any case if the substantive information contained in a report submitted with an exemption application is out of date.)

Conversely, where an independent fiduciary represents the plan in an exemption transaction, that fiduciary is subject to all of the responsibilities imposed by part 4 of subtitle B of title I of ERISA. None of the comments received questioned the need for such a fiduciary to provide the declaration under penalty of perjury required under the proposed regulation, and the Department has decided to retain this proposed requirement for such plan fiduciaries in the final regulation. As a result, the Department has modified § 2570.34(b)(5)(ii) and has added § 2570.34(b)(5)(iv) to clarify that a declaration is required for such plan fiduciaries.

Pooled Funds

One comment suggested that § 2570.35 of the proposed regulation be modified to provide a special rule regarding information to be included in an application for an individual exemption involving a pooled investment fund, such as a pooled separate account maintained by an insurance company or a collective investment fund maintained by another financial institution. The commentator pointed out that, as proposed, § 2570.35 would require information to be submitted regarding each plan participating in a pooled investment fund, resulting in the submission of an overwhelming volume of information unrelated to the exemption transaction. However, the commentator recognized that information regarding certain plans may be relevant to the exemption application in view of the potential for conflicts of interest involving such plans. Such plans would include any plan maintained for employees of the sponsor or other fiduciary of the pooled investment fund, and a plan whose participation in the pooled fund exceeded a specified percentage of the total fund assets.

The Department agrees with this comment and, accordingly, has added a new paragraph (c) to § 2570.35, which contains a special rule for applications for individual exemptions involving pooled funds [as defined in § 2570.31(g)]. Subparagraph (1) of § 2570.35(c) excepts such applications from including certain information otherwise required relating to among other things: reportable events under section 4043 of ERISA, notice of intent to terminate a plan (section 4041 of ERISA), the number of participants and beneficiaries of each plan participating in the pooled fund, and the percentage of each such plan's assets involved in the exemption transaction.

Subparagraph (2) of the special rule provides that certain information otherwise required by § 2570.35 (a) and (b) of the regulation must be furnished by reference to the pooled fund rather than the plans participating in such fund. This information pertains to: Identifying information; any prior violations of the Code's exclusive benefit rule or of the prohibited transaction provisions of the Code, ERISA or FERSA; any prior applications for exemption from such prohibited transaction provisions; any lawsuits or criminal actions regarding conduct with respect to any employee plan; any criminal convictions described in section 411 of ERISA; any investigation or continuing controversy with specified Federal agencies regarding compliance with ERISA, Code provisions relating to employee plans, or FERSA provisions relating to the Federal Thrift Savings Fund; whether the exemption transaction has been consummated and, if so, certain related information regarding correction of the prohibited transaction and payment of excise taxes; the identification of persons with investment discretion over any assets involved in the exemption transaction and each such person's relationship to the parties in interest involved in the exemption transaction; investments involving certain parties in interest; the fair market value of the pooled fund; the identity of the person who will pay the costs of the exemption application, notifying interested persons, and the fee of any independent fiduciary involved in the exemption transaction; and an analysis of the facts relevant to the exemption transaction as reflected in documents submitted with the application. The pooled fund, rather than participating plans, must also furnish copies of all relevant documents, including, for example, the most recent financial statements of the pooled fund.

Subparagraph (3) of the special rule requires information to be furnished with pooled fund exemption applications with respect to: the aggregate number of plans expected to participate in the pooled fund, and the limits (if any) imposed by the pooled fund on the amount or percentage of each participating plan's assets that may be invested in the pooled fund.

Subparagraph (4) of § 2570.35(c) contains additional requirements for applications for individual exemptions involving pooled funds. These requirements apply to plans whose investments in the pooled fund represent more than 20% of the pooled fund's total assets [6] and those plans covering employees of the pooled fund's sponsor, and other fiduciaries with discretion over pooled fund assets. The Department believes that additional information is warranted in those situations where the potential for decision making that may inure to the benefit of a fiduciary or other party in interest is increased. For each of these plans, the additional requirements provide for the furnishing of certain individual plan information described in § 2570.35(a), in addition to the information required under § 2570.35 (c)(2) and (c)(3). The Department believes this information is necessary for its determination as to whether sufficient protections are incorporated into the exemption transaction.

The Department further notes that the decision by the fiduciaries of certain plans to invest in a pooled fund may involve a separate prohibited transaction, apart from any prohibited transaction which may be entered into by the pooled fund itself. In this regard, the Department notes that the information required to be submitted on behalf of such plans is to be provided in accordance with the general rule contained in § 2570.35, rather than the special rule for pooled funds.

Finally, the Department believes that the special rule for pooled funds is less burdensome to applicants than the rules set forth in the proposed regulation. As noted by a commentator, the proposed regulation would have required the submission of voluminous amounts of material, as information would have to be submitted on behalf of each plan investing in a pooled fund. The final

[6] See section I(e) of PTE 84-14 (49 FR 9494, March 13, 1984) the class exemption involving qualified professional asset managers.

regulation limits the amount of material to be submitted since it requires only information relating to the pooled fund and, where applicable, certain plans investing in the pooled fund. In addition, the Department believes that its ability to analyze and process applications for exemption involving pooled funds will be enhanced by this special rule. In this regard, the Department believes that the final regulation eliminates a significant amount of material that otherwise would have been required.

Lawsuits, Certain Criminal Convictions, Investigations, Examinations, Continuing Controversies, etc.

Sections 2570.35(a) (5), (6), and (7) of the proposed regulation required exemption applications to disclose information regarding whether the applicant or any of the parties to the exemption transaction is or has been, within a specified number of years past, a defendant in any lawsuit or criminal action concerning conduct as a fiduciary or other party in interest with respect to any employee benefit plan (§ 2570.35(a)(5)), convicted of a crime described in section 411 of ERISA (§ 2570.35(a)(6)), or under investigation or examination or engaged in litigation or a continuing controversy with certain Federal agencies (§ 2570.35(a)(7)). Proposed § 2570.35(a)(7) also required disclosure of whether any plan affected by the exemption transaction has been under such investigation, examination, litigation, or continuing controversy, and further required the applicant to submit copies of all correspondence with the specified Federal agencies regarding substantive issues involved in such investigation, etc.

Two of the comments urged deletion of the disclosure requirements of proposed § 2570.35(a) (5) and (7) on the basis that such disclosure is difficult, costly, and almost always irrelevant to the exemption transaction.

The Department continues to believe that the proposed disclosure is relevant to the exemption transaction. With regard to § 2570.35(a)(5) (relating to lawsuits or certain criminal actions), the Department views the disclosure required as directly concerning the conduct of the applicant and other parties in interest participating in the exemption transaction. The Department believes that such information is necessary in evaluating the credibility and integrity of such parties, some of whom may possess substantial discretion regarding the exemption transaction or may make representations upon which the Department must rely in determining whether the statutory criteria for an exemption have been satisfied. In addition, the proposed disclosure assists the Department in ensuring that the exemption transaction contains appropriate safeguards.

Further, the Department does not agree that the disclosure required by § 2570.35(a)(5) imposes any significant burdens on applicants. The Department believes that prudent fiduciaries would, in the normal course of carrying out their responsibilities, ascertain such information about the parties they intend to deal with in investment and other plan transactions. However, the Department has determined that it would be appropriate to modify proposed § 2570.35(a)(5) in the final regulation to limit disclosure to the applicant or any of the parties in interest involved in the exemption transaction.

Regarding the disclosure required by proposed § 2570.35(a)(7) (relating to investigations, examinations, litigation, and continuing controversy by or with the specified Federal agencies), the Department believes that such information is necessary to ensure that the Department's exemption activities do not compromise its enforcement efforts. Although the Department is most interested in information involving investigations, etc. that are directly related to the subject exemption transactions and the participating parties, the Department believes, nevertheless, that its exemption staff, and not the applicants, should determine which investigations, examinations, etc, are relevant.

One of the comments further suggested that it is inappropriate to require applicants to disclose matters which have resulted in no formal allegations of violations of law. The Department notes, however, that the affected parties may include, as part of their disclosure, any qualifications or explanations they deem appropriate for consideration by the Department, including information on the final disposition of any matter.

Another commentator suggested that disclosure under § 2570.35(a)(7) be limited to a reference to the investigation or litigation without requiring submission of copies of "all correspondence" involved in the investigation. In this regard, the Department notes that the proposed regulation did not require submission of copies of all correspondence, but only of correspondence relating to the substantive issues involved in the investigation, examination, litigation, or controversy. Specifically, the Department intended to require submission of copies of correspondence containing only that information directly relevant to determining whether or not the requested exemption should be granted. After considering the comment, the Department has modified § 2570.35(a)(7) to clarify that the phrase "substantive issues" refers to issues related to compliance with the provisions of parts 1 and 4 of subtitle B of title I of ERISA (reporting and disclosure (part 1) and fiduciary responsibility (part 4)), section 4975 of the Code, or sections 8477 or 8478 of FERSA (fiduciary responsibilities, liability and penalties (section 8477) and bonding (section 8478)). Copies of correspondence relating to any of these substantive issues is necessary in order for the Department to determine the effect the requested exemption may have on the Department's enforcement activities in each case under investigation, examination, etc.

One of the comments noted that proposed § 2570.35(a)(5), (6), and (7) required the disclosure of information regarding any parties to the exemption transaction and suggested limiting the required disclosure to fiduciaries authorizing the transaction and any parties in interest involved in the exemption transaction. This comment pointed out that investment transactions may involve multiple parties, many of whom are neither plan fiduciaries nor parties in interest. After due consideration, the Department agrees with this suggestion and, accordingly, has modified § 2570.35(a)(5), (6), and (7) to limit the required disclosure to any parties in interest involved in the exemption transaction. The Department notes that this group includes, among others, the fiduciary authorizing the exemption transaction.

See the heading "Applications for Exemption under FERSA," above, regarding modification to proposed § 2570.35(a)(7) as applicable to the Federal Thrift Savings Plan established by FERSA.

Party-in-Interest Investments

Proposed § 2570.35(a)(16) required an application for individual exemption to disclose information regarding any plan investments in loans to, property leased to, or securities issued by, any party in interest involved in the exemption transaction. One of the comments suggested deletion of this requirement due to the difficulty of identifying such investments in view of the "look-through" rule contained in the Department's plan asset regulation (29 CFR 2510.3–101). This comment suggested that the proposed disclosure may involve many transactions, by an

entity whose underlying assets include "plan assets," which are totally unrelated to the exemption transaction. The comment further indicated that this disclosure would be burdensome for exemption transactions involving numerous parties in interest, such as those involving pooled funds.

The Department agrees that, for exemption applications involving pooled funds, furnishing the proposed disclosure could be burdensome inasmuch as such applications generally do not relate to specific plans. Accordingly, the Department has adopted a special rule for applications for individual exemption involving pooled funds, discussed above (under the heading "Pooled Funds"), which limits this type of disclosure to the pooled fund and to certain plans participating therein.

Regarding exemption applications involving specific individual plans, it appears to the Department that the information to be disclosed under proposed § 2570.35(a)(16) must be maintained, in any event, to satisfy the annual reporting requirements of section 103 of ERISA, as well as the recordkeeping requirements of section 107. Therefore, the Department believes that this disclosure requirement should not impose any additional burdens on the applicant. The information to be disclosed will enable the Department to determine whether the exemption transaction, in conjunction with other plan investments involving parties in interest, would unduly concentrate the plan's assets in such investments so as to raise questions under the fiduciary responsibility provisions of section 404 of ERISA. For these reasons, the Department has decided to adopt § 2570.35(a)(16) as proposed, subject to the special rule for applications for individual exemption involving pooled funds in § 2570.35(c).

Costs Related to the Exemption Application

Proposed § 2570.35(a)(18) and (19) required the exemption application to identify the person who will bear the costs of the exemption application, of notifying interested persons, and of the fee charged by any independent fiduciary involved in the exemption transaction. The preamble to the proposed regulation noted that a plan's payment of the expenses associated with the filing or processing of an exemption application raises questions under the fiduciary responsibility and the prohibited transaction restrictions to the extent that any party in interest benefits from the transaction for which an exemption is sought (see section 406(a)(1)(D) of ERISA).

One of the commentators requested that the Department provide a more specific discussion of when it believes such questions will be raised. The comment states that, in many cases, it is appropriate for the plan to pay the expenses attributable to obtaining an exemption, and that an independent fiduciary's fees are generally paid by the plan receiving such fiduciary's services in order to ensure that such fiduciary conducts its activities in a totally independent manner and without any potential influence from persons other than the plan paying such fees.

The proposed disclosure of who pays the fees for an exemption application is intended to enable the Department to review the appropriateness of such payment by a plan in the context of a specific exemption request. Such disclosure is also intended to aid the exemption staff in evaluating whether the economic merits of the transaction, taking into account the costs attributable to the exemption application, support a finding that the proposed transaction is in the interests of the plan and its participants and beneficiaries. While the Department agrees that there may be certain instances in which it would be appropriate for a plan to pay all or part of the costs attendant with obtaining an exemption, such as where it is necessary to ensure the independence of an independent fiduciary or third-party expert, the Department believes that the propriety of such payments by a plan is an inherently factual determination which can be made only on a case-by-case basis.

In this regard, the Department notes that, when evaluating the propriety of the payment by a plan of certain expenses, plan fiduciaries must first consider the general fiduciary responsibility provisions of sections 403 and 404 of ERISA. Section 403(c)(1) provides, in part, that the assets of an employee benefit plan shall never inure to the benefit of any employer and shall be held for the exclusive purpose of providing benefits to participants and beneficiaries and defraying reasonable expenses of administering the plan. Similarly, section 404(a)(1)(A) requires, in part, that a fiduciary of a plan discharge his duties for the exclusive purpose of providing benefits to participants and their beneficiaries and defraying reasonable expenses of administering the plan. Thus, a payment that is not a distribution of benefits to participants or beneficiaries of a plan would not be consistent with the requirements of sections 403(c)(1) and 404(a)(1)(A) unless it was used to defray a reasonable expense of administering the plan.

In addition, section 406(a)(1)(D) of ERISA prohibits a fiduciary with respect to a plan from causing the plan to engage in a transaction if he knows or should know that such transaction constitutes a direct or indirect transfer to, or use by or for the benefit of, a party in interest of any assets of the plan. It is the responsibility of appropriate plan fiduciaries to determine whether a particular expense is a reasonable administrative expense under sections 403(c)(1) and 404(a)(1)(A) of ERISA or whether plan payment of an expense would constitute a prohibited use of plan assets for the benefit of a party in interest under section 406(a)(1)(D) of ERISA.

Copies of Documents

Section 2570.35(b)(1) of the proposed regulation required each application for individual exemption to include true copies of all documents bearing on the exemption transaction, such as contracts, deeds, agreements, instruments, and relevant portions of plan documents, including trust agreements.

One comment objected to this requirement on the grounds that having to assemble the required documents is time consuming, costly, and unnecessary if the exemption application properly describes all pertinent plan provisions and other documents in sufficient detail to allow the Department to evaluate the merits of the exemption transaction. In this regard, the Department notes that the documents with respect to which copies are requested are all documents which would be readily available to the parties to the exemption transaction. Accordingly, the Department does not believe that there would be a significant burden in either compiling the documents or in transmitting copies to the Department. Further, the Department notes that it is not uncommon for representations contained in an exemption application to be inconsistent with the provisions of the governing documents or for the latter to contain provisions with respect to which clarifications or other representations are needed in order for the requested exemption to be proposed. On the basis of the Department's experience with exemptions, scrutiny of the relevant documents is, in the large majority of cases, a necessary prerequisite to a complete understanding of the exemption transaction and the implications for affected plans and

parties in interest. Moreover, in the Department's experience, the inclusion of copies of the requested documents, as part of the exemption application, has expedited the processing of the requested exemption.

For these reasons, the final regulation adopts proposed § 2570.35(b)(1) without change. However, the Department wishes to clarify three points regarding this requirement. First, for exemption transactions in which identical documents will be executed by more than one party, the submission of only one specimen document will satisfy the requirements of this paragraph.

Second, in the case of exemption transactions which are proposed, copies of the documents relating to the proposed transaction need not be executed or dated when they are submitted with the exemption application if the documents are complete in every other respect. In this regard, the Department strongly encourages requesting an administrative exemption before entering into a prohibited transaction because of the ability to incorporate all of the necessary safeguards into the transaction. By contrast, such safeguards cannot be put into place after a prohibited transaction has occurred.

Third, only copies of documents need be submitted. The Department may not be able to return original documents and, therefore, urges that only true copies of documents be submitted.

Where To File an Application

Although no comments were received regarding this section, which is adopted as proposed, the Department wishes to advise applicants that including the room number of the Division of Exemptions in the address will generally expedite its delivery. The current room number of the Division of Exemptions, Room N–5671, is not included in the regulation to avoid the need to amend the regulation every time the room number of the Division changes.

Duty To Amend and Supplement Information

The proposed regulation continued the requirement established in ERISA Proc. 75–1 that an applicant promptly notify the Division of Exemptions if he discovers that any material fact or representation contained in his application, or in any supporting documents or testimony, was inaccurate or if any such fact or representation changes. However, the proposed regulation added the requirement that an applicant notify the Division of Exemptions when anything occurs that may affect the continuing accuracy of such facts or representations.

Two comments received indicated confusion as to the expiration date of the duty to update information submitted as part of an exemption application. Accordingly, the final regulation clarifies § 2570.37 (a) and (b) to indicate that such duty applies only during the pendency of the exemption application and expires after the exemption is granted. The Department also wishes to clarify that, in § 2570.37(a), the phrase "continuing accuracy of any such fact or representation" refers to future events or changes known before the exemption is granted that will render inaccurate facts stated or representations made before such grant. The Department also wishes to note that exemptions are granted only to transactions as described. Therefore, if an exemption is granted and the transaction is not as described in some material aspect, the exemption does not take effect or protect parties in interest from liability for the transaction. See § 2570.49 of the regulation.

Tentative Denial Letters

Although ERISA Proc. 75–1 established no procedures to be followed by the Department in denying exemption applications or by applicants in responding to such denials, the Department has developed procedures over the years to notify applicants first to the tentative and, later, of the final denial of their applications. In large part, the proposed regulation codified these procedures.

Under the proposed regulation, the Department may decide to deny an exemption request at any one of a number of stages in the review process. For example, it may decide after its initial review of an application that the requested exemption does not satisfy the statutory criteria set forth in sections 408(a) of ERISA and 4975(c)(2) of the Code. In that event, the Department will send a tentative denial letter to the applicant pursuant to § 2570.38 of the regulation. That letter will inform the applicant of the Department's tentative decision to deny the application and of the reasons therefor. Under § 2570.38, an applicant has 20 days from the date of this letter to request a conference with the Department and/or to notify the Department of his intent to submit additional information in writing to support the application. If the Department receives no request for a conference and no notice of intent to submit additional information within that time, it will send the applicant a final denial letter pursuant to § 2570.41 of the regulation.

One of the comments received suggested that: (1) The final regulation should clarify that the Department's exemption staff may request applicants to provide additional information before a tentative denial letter is issued, and (2) rather than a "short statement" of the reasons for a tentative denial, the tentative denial letter should provide a detailed explanation of the basis for the Department's decision. Regarding the first suggestion, the comment indicates that it is unreasonable to expect an applicant to anticipate, when the exemption application is filed, all of the material which the Department may find pertinent to its consideration of an exemption application.

As stated above (under the heading "Exemption Application Contents—General Information"), the Department's view is that the applicant bears the responsibility to demonstrate clearly that the requested exemption meets the statutory criteria. While nothing in the proposed regulation would preclude the Department's exemption staff from exercising its discretion and contacting an applicant for a clarification or additional information, the Department anticipates that such contact will be limited to exemption applications which, upon initial review, meet the essential requirements of the regulation. It is not administratively feasible to expect the Department's exemption staff to solicit information in every case. Moreover, such a procedure would, in effect, shift the burden of developing the exemption application from the applicant to the exemption staff.

Similarly, the imposition of a requirement that tentative denial letters detail all the reasons for the denial would, in effect, shift the analytical burden from the applicant to the Department. As with the circumstances under which additional information is solicited from applicants, the Department believes that the degree of detail required for a tentative denial letter should be left to the discretion of the exemption staff. The Department believes that a general statement of the reasons for a tentative denial is sufficient inasmuch as the issuance of a tentative denial letter does not terminate the exemption proceedings. Rather, the tentative denial letter offers the applicant the opportunity to have a conference and/or to submit additional information for consideration. In addition, a requirement to issue a comprehensive and detailed tentative denial letter in most cases would

significantly increase the time required to conclude a final action.

For these reasons, the Department has decided to adopt proposed § 2570.38 without change.

Opportunities To Submit Additional Information

Section 2570.39 of the proposed regulation provided that if an applicant wishes to submit additional information in support of a tentatively denied exemption application, he may notify the Department of his intention to do so within the prescribed 20-day period either by telephone or by letter. After issuing such a notice, an applicant has 30 days from the date of the notice to furnish additional information to the Department. If an applicant notifies the Department of his intent to submit additional information but requests no conference, and subsequently fails to submit the promised information within the prescribed 30-day period, the Department will issue the applicant a final denial letter pursuant to § 2570.41 of the regulation. However, an applicant who realizes that he will be unable to submit his additional information within the allotted time may avoid receiving a final denial letter by withdrawing his application before the end of the 30-day period pursuant to § 2570.44.

As an alternative to withdrawing his application, an applicant who, for reasons beyond his control, is unable to meet the 30-day deadline may request an extension of time for filing additional information, pursuant to § 2570.39 of the regulation. However, the Department will grant such extensions of time only in unusual circumstances.

No comments were received on this section of the proposed regulation which is adopted without change in the final regulation.

Conferences

Section 2570.40 of the proposed regulation described the procedures regarding conferences on exemption applications which the Department has tentatively decided to deny. Under this proposed section, an applicant is entitled to only one conference with respect to any exemption application, and is also given 20 days after the date of any conference to submit to the Department in writing any additional data or arguments discussed at the conference but not previously or adequately presented in writing. Under the proposal, an applicant is deemed to have waived his right to a conference if he fails, without good cause, to appear for a scheduled conference or to schedule a conference for any of the times proposed by the Department within the 45-day period following the receipt of his request for a conference.

Proposed § 2570.40 is adopted without change in the final regulation. The only comment received regarding this proposed section suggested that the Department continue its practice of informally consulting with applicants on exemption applications in addition to holding conferences. In this regard, the Department will continue to informally contact applicants as it deems appropriate.

Final Denial Letters

Proposed § 2570.41 is adopted without change in the final regulation. No comments were received on this section which specifies the circumstances in which the Department may issue a final denial letter denying a requested exemption. In most cases, the same procedure will also be followed in denying exemptions that the Department has already proposed through publication of a notice of proposed exemption in the **Federal Register**. However, in cases where the Department holds a hearing on an exemption, § 2570.41(a)(3) of the proposed regulation allowed the Department to issue a final denial letter without first issuing a tentative denial letter and without providing the applicant with the opportunity for a conference. In the Department's view, where a hearing on a proposed exemption is conducted, the applicant and other proponents of the exemption have adequate opportunity to present their views and other evidence in support of the exemption.

Notice of Proposed Exemption

The proposed regulation did not significantly alter the procedures established by ERISA Proc. 75–1 for granting an exemption. Under § 2570.42 of the regulation, the Department will publish a notice of proposed exemption in the **Federal Register** if, after reviewing an exemption application and any additional information submitted by an applicant, the Department tentatively concludes that the requested exemption satisfies the statutory criteria for the granting of an exemption and that the requested exemption is otherwise appropriate. This proposed section also described the contents of the notice of proposed exemption.

No comments were received on proposed § 2570.42, which is adopted without change in the final regulation.

Notifying Interested Persons

Like ERISA Proc. 75–1, the proposed regulation required applicants to provide notice to interested persons in the event that the Department decides to propose the exemption. Section 2570.34 of the proposal required an applicant to submit with his application a description of the interested persons to whom notice will be provided and a description of the manner in which the applicant proposed to provide notice. That section also required an applicant to provide an estimate of the time he will need to furnish notice to interested persons following publication of a notice of proposed exemption.

Section 2570.43 of the proposed regulation provided guidance on methods an applicant may use to notify interested persons of a proposed exemption and indicated what must be included in the notice. In addition to the Notice of Proposed Exemption published in the **Federal Register**, the applicant must include in the notification to interested persons a supplemental statement. Section 2570.43 also stated that, once the Department has published a notice of proposed exemption, the applicant must notify the interested persons described in his application in the manner indicated in the application unless the Department has informed the applicant beforehand that it considers the method of notification described in the application to be inadequate. Where the Department has so informed an applicant, it will also secure from the applicant an agreement to provide notice in the time and manner and to the persons designated by the Department. After furnishing notification, an applicant must provide the Department with a declaration under penalty of perjury certifying that notice was given to the persons and in the manner and time specified in his application or the superseding agreement with the Department.

One of the comments received concerning notification requested clarification that, in the case of a pooled fund, the notification requirement would be satisfied if the notice to interested persons is furnished to the appropriate fiduciary of each of the plans participating in the pooled fund, but not to all participants and beneficiaries of such plans.

In the Department's view, the individuals or organizations that will constitute "interested persons" depends on the nature of the exemption being requested. For this reason, the proposed regulation did not attempt to delineate the term "interested persons" for purposes of the notification requirements of § 2570.43. As previously noted, the applicant is required to include, as part of the exemption application, a description of the

interested persons to whom the applicant intends to provide notice (§ 2570.34(b)(2)(i)). If the Department finds that either the method of providing the notice or the persons to whom the applicant proposes to provide notice is inadequate, the Department will, pursuant to § 2570.43, secure an agreement from the applicant on the appropriate method of providing the notice and/or the scope of the notice to be provided. The Department believes that this approach provides the flexibility necessary to accommodate the varied types of exemption applications, as well as circumstances unique to a particular applicant.[7]

Accordingly, the Department has decided to adopt § 2570.43 as proposed. However, subparagraph (b)(2) of this section has been modified to insert references to the Code and FERSA, and to reflect the current room number of the Division of Exemptions in a footnote to that section. Paragraph (d) of this section has also been modified to clarify that the declaration accompanying the statement to be furnished to the Department regarding the notice to interested persons must be made under penalty of perjury, as stated in the preamble to the proposed regulation (53 FR 24422, at 24425, June 28, 1988).

Withdrawal and Reinstatement of Exemption Applications

Section 2570.44 of the proposed regulation permitted an applicant to withdraw his application at any time and to reinstate the application later. Reinstatement may be requested without resubmitting any information or materials previously furnished if no more than two years has elapsed from the withdrawal date. The request for reinstatement must be accompanied by any additional information that was outstanding at the time of withdrawal.

No comments were received on this proposed section, which is adopted in the final regulation without change.

Requests for Reconsideration of Final Denials

Under § 2570.45 of the proposed regulation, after the Department has issued a final denial letter on an exemption, it will not reconsider an application covering the same transaction unless the applicant presents significant new facts or arguments in support of the exemption which, for good reason, the applicant could not have submitted for consideration during the Department's initial review of the exemption application. An applicant must present the significant new facts or arguments in a request for reconsideration within 180 days after the issuance of the final denial letter.

Proposed § 2570.45 also stated that only one request for reconsideration of any finally denied application will be considered by the Department. Although no comments were received on this section of the proposed regulation, the Department has modified this section in the final regulation to clarify that the Department will not limit the number of requests for reconsideration of final denials based solely on the applicant's failure to respond timely to a tentative denial letter or to furnish additional information timely (i.e., within the time frames provided under §§ 2570.38(b) or 2570.39(e), respectively).

The Department has also clarified in the final regulation that the declaration required under § 2570.45(c) must be made under penalty of perjury. This clarification is consistent with the requirement of § 2570.34(b)(5) that every original exemption application must be accompanied by a similar declaration under penalty of perjury. The Department intends that the same type of declaration should accompany both an original exemption application and a request for reconsideration of a final denial based on the merits of such an application.

Hearings

Section 408(a) of ERISA precludes the Department from granting an exemption from the fiduciary self-dealing prohibitions of section 406(b) unless the Department affords an opportunity for a hearing and makes a determination on the record with respect to the three statutory criteria established for granting an exemption.[8] Because these provisions specify that an opportunity for a hearing must be given before an exemption from these prohibitions is granted, but not before such an exemption is denied, the Department interprets these provisions to mean that only opponents of such an exemption must be given an opportunity for a hearing. Moreover, the Department has concluded that it must provide a hearing on the record to opponents of such a proposed exemption only where it appears that there are material factual issues relating to the proposed exemption that cannot be fully explored without such a hearing. Indeed, in the Department's experience, such hearings are not useful where the only issues to be decided are matters of law or where material factual issues can be adequately explored by less costly and more expeditious means, such as written submissions. Accordingly, under § 2570.46 of the proposed regulation, the Department requires that persons who may be adversely affected by the grant of an exemption from the fiduciary self-dealing prohibitions offer some evidence of the existence of issues that can be fully examined only at a hearing before it will grant a request for a hearing. Where persuasive evidence of the existence of such issues is offered, however, the Department will grant the requested hearing.

Under § 2570.47 of the proposed regulation, the Department may schedule a hearing on its own motion if it determines that a hearing would be useful in exploring issues relevant to the requested exemption. Under the proposed procedures, if the Department decides to conduct a hearing on an exemption under either § 2570.46 or § 2570.47, the applicant must notify interested persons of the hearing in the manner prescribed by the Department. Ordinarily, such notice may be provided by furnishing interested persons with a copy of the notice of hearing published by the Department in the **Federal Register** within 10 days of its publication. After furnishing notice, the applicant must submit to the Department a declaration under penalty of perjury certifying that notice has been provided in the manner prescribed.

Any testimony or other evidence offered at a hearing held under either § 2570.46 or § 2570.47 becomes part of the administrative record to be used by the Department in making its final decision on an exemption application.

No comments were received on proposed §§ 2570.46 and 2570.47, which are adopted without change in the final regulation.

Grant of Exemption

Section 2570.48 of the proposed regulation provided that if, after considering all of an applicant's submissions, together with any comments received from interested persons and the record of any hearing held in connection with a requested exemption, the Department determines that the exemption should be granted, it will publish a notice in the **Federal Register** granting the exemption. This proposed section also described the contents of the grant notice.

[7] The Department notes that the form of the notice is prescribed under § 2570.43(b) of the regulation.

[8] Section 4975(c)(2) of the Code and 5 U.S.C. 8477(c)(3)(D) (added by FERSA) contain similar hearing requirements. The following discussion of the hearing requirements of section 408(a) of ERISA is equally applicable to those statutory provisions.

No comments were received on proposed § 2570.48, which is adopted without change in the final regulation.

Limits on the Effect of Exemptions

Notwithstanding the duty to amend and supplement exemption applications provided under § 2570.37, the Department expressly conditions every exemption on the accuracy and completeness of the facts and representations provided by an applicant in support of the exemption. Therefore, as indicated under § 2570.49 of the proposed regulation, an exemption does not take effect or protect parties in interest from liability unless the material facts and representations contained in the application or in any other materials, documents, or testimony submitted by the applicant in support of the application were true and complete.

Thus, for example, in the case of a continuing exemption transaction such as a loan or a lease, if any of the material facts described in the application were to change after the exemption is granted, the exemption would cease to apply as of the date of such change even though, pursuant to § 2570.37, the applicant would not be obligated to notify the Department of such change. In the event of any such change, the parties in interest involved in the exemption transaction may apply for a new exemption to protect themselves from liability on or after the date of such change. Such an application should be submitted before such change occurs (see the discussion of prospective, versus retroactive, exemptions under the heading "Copies of Documents," above).

No comments were received on proposed § 2570.49, which is adopted without change in the final regulation.

Revocation or Modification of Exemptions

Section 2570.50 of the proposed regulation described the circumstances under which the Department may revoke or modify a previously granted exemption and the rights afforded to the applicant and to other interested persons in the event such revocation or modification is proposed. This section also provided that ordinarily such revocation or modification will be prospective only. Under this proposed section, one of the circumstances permitting the Department to modify or revoke an exemption was a change in policy which calls into question the continuing validity of the Department's original conclusions regarding the granted exemption.

Two of the comments objected to permitting a change in policy as grounds for revoking or modifying a granted exemption. The commentators argued that disturbing transactions already reviewed and approved by the Department would inject an unneeded element of uncertainty into the exemption process. Moreover, concern was expressed that the revocation of an exemption could severely disrupt an applicant's business and impose great financial hardship. A commentator suggested that the final regulation include a prohibition against revocation of an exemption until the affected party in interest is given both written notice of the facts or conduct which may warrant the revocation and an opportunity to demonstrate compliance with the requirements of the exemption.[9]

Proposed § 2570.50 is intended to provide the Department with the flexibility to undertake appropriate action in those cases where, subsequent to the grant of an exemption, potentially abusive practices or changes in the regulatory environment of an industry are identified which would cause the Department to reconsider its policy with respect to whether the exemption transactions continue to satisfy the statutory criteria under section 408(a) of ERISA.

With regard to the procedural issues raised by one of the comments, the Department notes that paragraph (b) of proposed § 2570.50 provides for notice to interested persons by publication in the **Federal Register**, notice to the applicant of the proposed revocation or modification, and an opportunity for the interested persons and the applicant to submit comments on the proposed revocation or modification.

After careful consideration of the comments, the Department has decided to adopt § 2570.50 as proposed. However the Department has clarified paragraph (b) to provide that the notice of proposed revocation or modification given to the applicant must be in writing.

Public Inspection and Copies

Section 2570.51 of the proposed regulation provided that the public may examine and copy any exemption application and all correspondence and documents submitted in regard thereto and may receive photocopies of all or any portion of such administrative record for a specified charge per page. For this reason, the Department cannot honor requests to keep confidential any information submitted regarding an exemption application. Therefore, none of the information submitted in regard to a requested exemption should be material that the applicant or other sender does not wish to disclose to the public.

No comments were received on proposed § 2570.51, which is adopted without change in the final regulation.

Executive Order 12291 Statement

The Department has determined that this regulatory action would not constitute a "major rule" as that term is used in Executive Order 12291 because the action would not result in: an annual effect on the economy of $100 million; a major increase in costs or prices for consumers, individual industries, government agencies, or geographical regions; or significant adverse effects on competition, employment, investment, productivity, innovation, or on the ability of United States-based enterprises to compete with foreign-based enterprises in the domestic or export markets.

Regulatory Flexibility Act Statement

The Department has determined that this regulation would not have a significant economic impact on small plans or other small entities. As stated previously, this regulation would do little more than describe procedures that reflect practices already in place for filing and processing applications for exemptions from the prohibited transaction provisions of the Employee Retirement Income Security Act of 1974, the Internal Revenue Code of 1986, and the Federal Employee Retirement System Act of 1986.

Paperwork Reduction Act

This regulation modifies current collection of information requirements. It does so largely by codifying requests for facts and opinions that are routinely addressed to applicants for exemptions under current procedures. Accordingly, the regulation will not increase the paperwork burden for applicants. The regulation has been approved by the Office of Management and Budget under the provisions of the Paperwork Reduction Act of 1980 (Pub. L. 96–511). The final regulation is assigned control number 1210–0060.

Authority

The final regulation set forth herein is issued pursuant to the authority granted

[9] This comment compares the revocation of an exemption to the revocation of a license granted by an agency of the United States Government pursuant to 5 U.S.C. 558(c). The Department is expressing no opinion herein as to the applicability of 5 U.S.C. 558(c) to the revocation of prohibited transaction exemptions under ERISA, the Code, or FERSA.

in sections 408(a) (Pub. L. 93–406, 88 Stat. 883, 29 U.S.C. 1108(a)) and 505 (Pub. L. 93–406, 88 Stat. 894, 29 U.S.C. 1135) of ERISA, under Reorganization Plan No. 4 of 1978 (43 FR 47713, October 17, 1978), under 5 U.S.C. 8477(c)(3), and under Secretary of Labor's Order No. 1–87 (52 FR 13139, April 21, 1987).

List of Subjects in 29 CFR Part 2570

Administrative practice and procedure, Employee benefit plans, Employee Retirement Income Security Act, Federal Employees' Retirement System Act, Party in interest, Pensions, Prohibited transactions.

Final Regulation

For the reasons set out in the preamble, parts 2570 and 2585 of chapter XXV of title 29 of the Code of Federal Regulations are amended as follows:

PART 2570—[AMENDED]

1. The authority for part 2570 is revised to read as follows:

Authority: 29 U.S.C. 1108(a), 1135; Reorganization Plan No. 4 of 1978; 5 U.S.C. 8477(c)(3); Secretary of Labor's Order No. 1–87.

Subpart A is also issued under 29 U.S.C. 1132(i).

2. By adding in the appropriate place the following new subpart B to part 2570.

Subpart B—Procedures for Filing and Processing Prohibited Transaction Exemption Applications

Sec.

2570.30 Scope of rules.
2570.31 Definitions.
2570.32 Persons who may apply for exemptions.
2570.33 Applications the Department will not ordinarily consider.
2570.34 Information to be included in every exemption application.
2570.35 Information to be included in applications for individual exemptions only.
2570.36 Where to file an application.
2570.37 Duty to amend and supplement exemption applications.
2570.38 Tentative denial letters.
2570.39 Opportunities to submit additional information.
2570.40 Conferences.
2570.41 Final denial letters.
2570.42 Notice of proposed exemption.
2570.43 Notification of interested persons by applicant.
2570.44 Withdrawal of exemption applications.
2570.45 Requests for reconsideration.
2570.46 Hearings in opposition to exemptions from restrictions on fiduciary self-dealing.
2570.47 Other hearings.
2570.48 Decision to grant exemptions.
2570.49 Limits on the effect of exemptions.
2570.50 Revocation or modification of exemptions.
2570.51 Public inspection and copies.
2570.52 Effective date.

Subpart B—Procedures for Filing and Processing Prohibited Transaction Exemption Applications

§ 2570.30 Scope of rules.

(a)(1) The rules of procedure set forth in this subpart apply to all applications for exemption which the Department has authority to issue under:

(i) Section 408(a) of the Employee Retirement Income Security Act of 1974 (ERISA);

(ii) Section 4975(c)(2) of the Internal Revenue Code of 1986 (the Code) (see Reorganization Plan No. 4 of 1978); or

(iii) The Federal Employees' Retirement System Act of 1986 (FERSA) (5 U.S.C. 8477(c)(3)).

(b) The Department will generally treat any exemption application which is filed solely under section 408(a) of ERISA or solely under section 4975(c)(2) of the Code as an exemption filed under both section 408(a) and section 4975(c)(2) if it relates to a transaction that would be prohibited both by ERISA and by the corresponding provisions of the Code.

(c) The procedures set forth in this subpart represent the exclusive means by which the Department will issue administrative exemptions. The Department will not issue exemptions upon oral request alone. Likewise, the Department will not grant exemptions orally. An applicant for an administrative exemption may request and receive oral advice from Department employees in preparing an exemption application. However, such advice does not constitute part of the administrative record and is not binding on the Department in its processing of an exemption application or in its examination or audit of a plan.

§ 2570.31 Definitions.

For purposes of these procedures, the following definitions apply:

(a) An *affiliate* of a person means—

(1) Any person directly or indirectly through one or more intermediaries, controlling, controlled by, or under common control with the person;

(2) Any director of, relative of, or partner in, any such person;

(3) Any corporation, partnership, trust, or unincorporated enterprise of which such person is an officer, director, or a 5 percent or more partner or owner; and

(4) Any employee or officer of the person who—

(i) Is highly compensated (as defined in section 4975(e)(2)(H) of the Code), or

(ii) Has direct or indirect authority, responsibility, or control regarding the custody, management, or disposition of plan assets.

(b) A *class exemption* is an administrative exemption, granted under section 408(a) of ERISA, section 4975(c)(2) of the Code, and/or 5 U.S.C. 8477(c)(3), which applies to any parties in interest within the class of parties in interest specified in the exemption who meet the conditions of the exemption.

(c) *Department* means the U.S. Department of Labor and includes the Secretary of Labor or his delegate exercising authority with respect to prohibited transaction exemptions to which this subpart applies.

(d) *Exemption transaction* means the transaction or transactions for which an exemption is requested.

(e) An *individual exemption* is an administrative exemption, granted under section 408(a) of ERISA, section 4975(c)(2) of the Code, and/or 5 U.S.C. 8477(c)(3), which applies only to the specific parties in interest named or otherwise defined in the exemption.

(f) A *party in interest* means a person described in section 3(14) of ERISA or 5 U.S.C. 8477(a)(4) and includes a *disqualified person*, as defined in section 4975(e)(2) of the Code.

(g) *Pooled fund* means an account or fund for the collective investment of the assets of two or more unrelated plans, including (but not limited to) a pooled separate account maintained by an insurance company and a common or collective trust fund maintained by a bank or similar financial institution.

§ 2570.32 Persons who may apply for exemptions.

(a) The Department may initiate exemption proceedings on its own motion. In addition, the Department will initiate exemption proceedings upon the application of:

(1) Any party in interest to a plan who is or may be a party to the exemption transaction;

(2) Any plan which is a party to the exemption transaction; or

(3) In the case of an application for an exemption covering a class of parties in interest or a class of transactions, in addition to any person described in paragraphs (a)(1) and (a)(2) of this section, an association or organization representing parties in interest who may be parties to the exemption transaction.

(b) An application by or for a person described in paragraph (a) of this section, may be submitted by the applicant or by his authorized representatives. If the application is submitted by a representative of the

applicant, the representative must submit proof of his authority in the form of:

(1) A power of attorney; or

(2) A written certification from the applicant that the representation is authorized.

(c) If the authorized representative of an applicant submits an application for an exemption to the Department together with proof of his authority to file the application as required by paragraph (b) of this section, the Department will direct all correspondence and inquiries concerning the application to the representative unless requested to do otherwise by the applicant.

§ 2570.33 Applications the Department will not ordinarily consider.

(a) The Department will not ordinarily consider:

(1) An application that fails to include all the information required by §§ 2570.34 and 2570.35 or otherwise fails to conform to the requirements of these procedures; or

(2) An application for exemption involving a transaction or transactions which are the subject of an investigation for possible violations of part 1 or 4 of subtitle B of title I of ERISA or section 8477 or 8478 of FERSA or an application for an exemption involving a party in interest who is the subject of such an investigation or who is a defendant in an action by the Department or the Internal Revenue Service to enforce the above-mentioned provisions of ERISA or FERSA.

(b) If for any reason the Department decides not to consider an exemption application, it will inform the applicant of that decision in writing and of the reasons therefor.

(c) An application for an individual exemption relating to a specific transaction or transactions will ordinarily not be considered separately if the Department is considering a class exemption relating to the same type of transaction or transactions.

§ 2570.34 Information to be included in every exemption application.

(a) All applications for exemptions must contain the following information:

(1) The name(s) of the applicant(s);

(2) A detailed description of the exemption transaction and the parties in interest for whom an exemption is requested, including a description of any larger integrated transaction of which the exemption transaction is a part;

(3) Whether the affected plan(s) and any parties in interest will be represented by the same person with regard to the exemption application;

(4) Reasons a plan would have for entering into the exemption transaction;

(5) The prohibited transaction provisions from which exemptive relief is requested and the reason why the transaction would violate each such provision;

(6) Whether the exemption transaction is customary for the industry or class involved;

(7) Whether the exemption transaction is or has been the subject of an investigation or enforcement action by the Department or by the Internal Revenue Service; and

(8) The hardship or economic loss, if any, which would result to the person or persons on behalf of whom the exemption is sought, to affected plans, and to their participants and beneficiaries from denial of the exemption.

(b) All applications for exemption must also contain the following:

(1) A statement explaining why the requested exemption would be—

(i) Administratively feasible;

(ii) In the interests of affected plans and their participants and beneficiaries; and

(iii) Protective of the rights of participants and beneficiaries of affected plans.

(2) With respect to the notification of interested persons required by § 2570.43:

(i) A description of the interested persons to whom the applicant intends to provide notice;

(ii) The manner in which the applicant will provide such notice; and

(iii) An estimate of the time the applicant will need to furnish notice to all interested persons following publication of a notice of the proposed exemption in the **Federal Register**.

(3) If an advisory opinion has been requested with respect to any issue relating to the exemption transaction—

(i) A copy of the letter concluding the Department's action on the advisory opinion request; or

(ii) If the Department has not yet concluded its action on the request:

(A) A copy of the request or the date on which it was submitted together with the Department's correspondence control number as indicated in the acknowledgment letter; and

(B) An explanation of the effect of a favorable advisory opinion upon the exemption transaction.

(4) If the application is to be signed by anyone other than an individual party in interest seeking exemptive relief on his own behalf, a statement which—

(i) Identifies the individual who will be signing the application and his position with the applicant; and

(ii) Explains briefly the basis of his familiarity with the matters discussed in the application.

(5)(i) A declaration in the following form: Under penalty of perjury, I declare that I am familiar with the matters discussed in this application and, to the best of my knowledge and belief, the representations made in this application are true and correct.

(ii) This declaration must be dated and signed by:

(A) The applicant himself in the case of an individual party in interest seeking exemptive relief on his own behalf;

(B) A corporate officer or partner where the applicant is a corporation or partnership;

(C) A designated officer or official where the applicant is an association, organization or other unincorporated enterprise;

(D) The plan fiduciary who has the authority, responsibility, and control with respect to the exemption transaction where the applicant is a plan.

(iii) Specialized statements from third-party experts, such as appraisals or analyses of market conditions, submitted to support an application for exemption must also be accompanied by a statement of consent from such expert acknowledging that he or she knows that his or her statement is being submitted to the Department as part of an application for exemption.

(iv) For those applications requiring an independent fiduciary to represent the plan in the exemption transaction, each statement submitted by said independent fiduciary must contain a signed and dated declaration under penalty of perjury that, to the best of said fiduciary's knowledge and belief, the representations made in such statement are true and correct.

(c) An application for exemption may also include a draft of the requested exemption which defines the transaction and parties in interest for which exemptive relief is sought and the specific conditions under which the exemption would apply.

§ 2570.35 Information to be included in applications for individual exemptions only.

(a) Except as provided in paragraph (c) of this section, every application for an individual exemption must include, in addition to the information specified in § 2570.34, the following information:

(1) The name, address, telephone number, and type of plan or plans to which the requested exemption applies;

(2) The Employer Identification Number (EIN) and the plan number (PN) used by such plan or plans in all

reporting and disclosure required by the Department;

(3) Whether any plan or trust affected by the requested exemption has ever been found by the Department, the Internal Revenue Service, or by a court to have violated the exclusive benefit rule of section 401(a) of the Code, or to have engaged in a prohibited transaction under section 503(b) of the Code or corresponding provisions of prior law, section 4975(c)(1) of the Code, section 406 or 407(a) of ERISA, or 5 U.S.C. 8477(c)(3);

(4) Whether any relief under section 408(a) of ERISA, section 4975(c)(2) of the Code, or 5 U.S.C. 8477(c)(3) has been requested by, or provided to, the applicant or any of the parties on behalf of whom the exemption is sought and, if so, the exemption application number or the prohibited transaction exemption number;

(5) Whether the applicant or any of the parties in interest involved in the exemption transaction is currently, or has been within the last five years, a defendant in any lawsuit or criminal action concerning such person's conduct as a fiduciary or party in interest with respect to any plan;

(6) Whether the applicant or any of the parties in interest involved in the exemption transaction has, within the last 13 years, been convicted of any crime described in section 411 of ERISA;

(7) Whether, within the last five years, any plan affected by the exemption transaction or any party in interest involved in the exemption transaction has been under investigation or examination by, or has been engaged in litigation or a continuing controversy with, the Department, the Internal Revenue Service, the Justice Department, the Pension Benefit Guaranty Corporation, or the Federal Retirement Thrift Investment Board involving compliance with provisions of ERISA, provisions of the Code relating to employee benefit plans, or provisions of FERSA relating to the Federal Thrift Savings Fund. If so, the applicant must submit copies of all correspondence with the Department, the Internal Revenue Service, the Justice Department, the Pension Benefit Guaranty Corporation, or the Federal Retirement Thrift Investment Board regarding the substantive issues involved in the investigation, examination, litigation, or controversy which relate to compliance with the provisions of part 1 or 4 of subtitle B of title I of ERISA, section 4975 of the Code, or section 8477 or 8478 of FERSA. For this purpose, the term "examination" does not include routine audits conducted by the Department pursuant to section 8477(g) of FERSA;

(8) Whether any plan affected by the requested exemption has experienced a reportable event under section 4043 of ERISA;

(9) Whether a notice of intent to terminate has been filed under section 4041 of ERISA respecting any plan affected by the requested exemption;

(10) Names, addresses, and taxpayer identifying numbers of all parties in interest involved in the subject transaction;

(11) The estimated number of participants and beneficiaries in each plan affected by the requested exemption as of the date of the application;

(12) The percentage of the fair market value of the total assets of each affected plan that is involved in the exemption transaction;

(13) Whether the exemption transaction has been consummated or will be consummated only if the exemption is granted;

(14) If the exemption transaction has already been consummated:

(i) The circumstances which resulted in plan fiduciaries causing the plan(s) to engage in the subject transaction before obtaining an exemption from the Department;

(ii) Whether the transaction has been terminated;

(iii) Whether the transaction has been corrected as defined in Code section 4975(f)(5);

(iv) Whether Form 5330, Return of Excise Taxes Related to Employee Benefit Plans, has been filed with the Internal Revenue Service with respect to the transaction; and

(v) Whether any excise taxes due under section 4975(a) and (b) of the Code by reason of the transaction have been paid.

(15) The name of every person who has investment discretion over any assets involved in the exemption transaction and the relationship of each such person to the parties in interest involved in the exemption transaction and the affiliates of such parties in interest;

(16) Whether or not the assets of the affected plan(s) are invested in loans to any party in interest involved in the exemption transaction, in property leased to any such party in interest, or in securities issued by any such party in interest, and, if such investments exist, a statement for each of these three types of investments which indicates:

(i) The type of investment to which the statement pertains;

(ii) The aggregate fair market value of all investments of this type as reflected in the plan's most recent annual report;

(iii) The approximate percentage of the fair market value of the plan's total assets as shown in such annual report that is represented by all investments of this type; and

(iv) The statutory or administrative exemption covering these investments, if any.

(17) The approximate aggregate fair market value of the total assets of each affected plan;

(18) The person(s) who will bear the costs of the exemption application and of notifying interested persons; and

(19) Whether an independent fiduciary is or will be involved in the exemption transaction and, if so, the names of the persons who will bear the cost of the fee payable to such fiduciary.

(b) Each application for an individual exemption must also include:

(1) True copies of all contracts, deeds, agreements, and instruments, as well as relevant portions of plan documents, trust agreements, and any other documents bearing on the exemption transaction;

(2) A discussion of the facts relevant to the exemption transaction that are reflected in these documents and an analysis of their bearing on the requested exemption; and

(3) A copy of the most recent financial statements of each plan affected by the requested exemption.

(c) *Special rule for applications for individual exemption involving pooled funds*:

(1) The information required by paragraphs (a) (8) through (12) of this section is not required to be furnished in an application for individual exemption involving one or more pooled funds;

(2) The information required by paragraphs (a) (1) through (7) and (a) (13) through (19) of this section and by paragraphs (b) (1) through (3) of this section must be furnished by reference to the pooled fund, rather than to the plans participating therein. (For purposes of this paragraph, the information required by paragraph (a) (16) of this section relates solely to other pooled fund transactions with, and investments in, parties in interest involved in the exemption transaction which are also sponsors of plans which invest in the pooled fund.);

(3) The following information must also be furnished—

(i) The estimated number of plans that are participating (or will participate) in the pooled fund; and

(ii) The minimum and maximum limits imposed by the pooled fund (if any) on

the portion of the total assets of each plan that may be invested in the pooled fund.

(4) Additional requirements for applications for individual exemption involving pooled funds in which certain plans participate.

(i) This paragraph applies to any application for individual exemption involving one or more pooled funds in which any plan participating therein—

(A) Invests an amount which exceeds 20% of the total assets of the pooled fund, or

(B) Covers employees of:

(*I*) The party sponsoring or maintaining the pooled fund, or any affiliate of such party, or

(*II*) Any fiduciary with investment discretion over the pooled fund's assets, or any affiliate of such fiduciary.

(ii) The exemption application must include, with respect to each plan described in paragraph (c)(4)(i) of this section, the information required by paragraphs (a) (1) through (3), (a) (5) through (7), (a) (10), (a) (12) through (16) and, (a) (18) and (19), of this section. The information required by this paragraph must be furnished by reference to the plan's investment in the pooled fund (e.g., the names, addresses and taxpayer identifying numbers of all fiduciaries responsible for the plan's investment in the pooled fund [§ 2570.35(a) (10)], the percentage of the assets of the plan invested in the pooled fund [§ 2570.35(a) (12)], whether the plan's investment in the pooled fund has been consummated or will be consummated only if the exemption is granted [§ 2570.35(a) (13)], etc.).

(iii) The information required by paragraph (c) (4) of this section is in addition to the information required by paragraphs (c) (2) and (3) of this section relating to information furnished by reference to the pooled fund.

(5) The special rule and the additional requirements described in paragraphs (c) (1) through (4) of this section do not apply to an individual exemption request solely for the investment by a plan in a pooled fund. Such an application must provide the information required by paragraphs (a) and (b) of this section.

§ 2570.36 Where to file an application.

The Department's prohibited transaction exemption program is administered by the Pension and Welfare Benefits Administration (PWBA). Any exemption application governed by these procedures should be mailed or otherwise delivered to: Exemption Application, PWBA, Office of Exemption Determinations, Division of Exemptions, U.S. Department of Labor, 200 Constitution Avenue NW., Washington, DC 20210.

§ 2570.37 Duty to amend and supplement exemption applications.

(a) During the pendency of his exemption application, an applicant must promptly notify the Division of Exemptions in writing if he discovers that any material fact or representation contained in his application or in any documents or testimony provided in support of the application is inaccurate, if any such fact or representation changes during this period, or if, during the pendency of the application, anything occurs that may affect the continuing accuracy of any such fact or representation.

(b) If, at any time during the pendency of his exemption application, an applicant or any other party in interest who would participate in the exemption transaction becomes the subject of an investigation or enforcement action by the Department, the Internal Revenue Service, the Justice Department, the Pension Benefit Guaranty Corporation, or the Federal Retirement Thrift Investment Board involving compliance with provisions of ERISA, provisions of the Code relating to employee benefit plans, or provisions of FERSA relating to the Federal Thrift Savings Fund, the applicant must promptly notify the Division of Exemptions.

(c) The Department may require an applicant to provide documentation it considers necessary to verify any statements contained in the application or in supporting materials or documents.

§ 2570.38 Tentative denial letters.

(a) If, after reviewing an exemption file, the Department concludes that it will not grant the exenption, it will notify the applicant in writing of its tentative denial of the exemption application. At the same time, the Department will provide a short statement of the reasons for its tentative denial.

(b) An applicant will have 20 days from the date of a tentative denial letter to request a conference under § 2570.40 of these procedures and/or to notify the Department of its intent to submit additional information in writing under § 2570.39 of these procedures. If the Department does not receive a request for a conference or a notification of intent to submit additional information within that time, it will issue a final denial letter pursuant to § 2570.41.

(c) The Department need not issue a tentative denial letter to an applicant before issuing a final denial letter where the Department has conducted a hearing on the exemption pursuant to either § 2570.46 or § 2570.47 of these procedures.

§ 2570.39 Opportunities to submit additional information.

(a) An applicant may notify the Department of its intent to submit additional information supporting an exemption application either by telephone or by letter sent to the address furnished in the applicant's tentative denial letter. At the same time, the applicant should indicate generally the type of information that he will submit.

(b) An applicant will have 30 days from the date of the notification discussed in paragraph (a) of this section to submit in writing all of the additional information he intends to provide in support of his application. All such information must be accompanied by a declaration under penalty of perjury attesting to the truth and correctness of the information provided, which is dated and signed by a person qualified under § 2570.34(b)(5) of these procedures to sign such a declaration.

(c) If, for reasons beyond his control, an applicant is unable to submit in writing all the additional information he intends to provide in support of his application within the 30-day period described in paragraph (b) of this section, he may request an extension of time to furnish the information. Such requests must be made before the expiration of the 30-day period and will be granted only in unusual circumstances and for limited periods of time.

(d) If an applicant is unable to submit all of the additional information he intends to provide in support of his exemption application within the 30-day period specified in paragraph (b) of this section, or within any additional period of time granted to him pursuant to paragraph (c) of this section, the applicant may withdraw the exemption application before expiration of the applicable time period and reinstate it later pursuant to § 2570.44 of these procedures.

(e) The Department will issue, without further notice, a final denial letter denying the requested exemption pursuant to § 2570.41 of these procedures where—

(1) The Department has not received the additional information that the applicant indicated he would submit within the 30-day period described in paragraph (b) of this section, or within any additional period of time granted pursuant to paragraph (c) of this section;

(2) The applicant did not request a conference pursuant to § 2570.38(b) of these procedures; and

(3) The applicant has not withdrawn his application as permitted by paragraph (d) of this section.

§ 2570.40 Conferences.

(a) Any conference between the Department and an applicant pertaining to a requested exemption will be held in Washington, DC, except that a telephone conference will be held at the applicant's request.

(b) An applicant is entitled to only one conference with respect to any exemption application. An applicant will not be entitled to a conference, however, where the Department has held a hearing on the exemption under either § 2570.46 or § 2570.47 of these procedures.

(c) Insofar as possible, conferences will be scheduled as joint conferences with all applicants present where:

(1) More than one applicant has requested an exemption with respect to the same or similar types of transactions;

(2) The Department is considering the applications together as a request for a class exemption;

(3) The Department contemplates not granting the exemption; and

(4) More than one applicant has requested a conference.

(d) The Department will attempt to schedule a conference under this section for a mutually convenient time during the 45-day period following the later of—

(1) The date the Department receives the applicant's request for a conference, or

(2) The date the Department notifies the applicant, after reviewing additional information submitted pursuant to § 2570.39, that it is still not prepared to propose the requested exemption.

If the applicant is unable to attend a conference at any of the times proposed by the Department during this 45-day period or if the applicant fails to appear for a scheduled conference, he will be deemed to have waived his right to a conference unless circumstances beyond his control prevent him from scheduling a conference or attending a scheduled conference within this period.

(e) Within 20 days after the date of any conference held under this section, the applicant may submit to the Department a written record of any additional data, arguments, or precedents discussed at the conference but not previously or adequately presented in writing.

§ 2570.41 Final denial letters.

(a) The Department will issue a final denial letter denying a requested exemption where:

(1) The conditions for issuing a final denial letter specified in § 2570.38(b) or § 2570.39(e) of these procedures are satisfied;

(2) After issuing a tentative denial letter under § 2570.38 of this part and considering the entire record in the case, including all written information submitted pursuant to § 2570.39 and § 2570.40(e) of these procedures, the Department decides not to propose an exemption or to withdraw an exemption already proposed; or

(3) After proposing an exemption and conducting a hearing on the exemption under either § 2570.46 or § 2570.47 of this part and after considering the entire record in the case, including the record of the hearing, the Department decides to withdraw the proposed exemption.

§ 2570.42 Notice of proposed exemption.

If the Department tentatively decides, based on all the information submitted by an applicant, that the exemption should be granted, it will publish a notice of proposed exemption in the **Federal Register**. The notice will:

(a) Explain the exemption transaction and summarize the information received by the Department in support of the exemption;

(b) Specify any conditions under which the exemption is proposed;

(c) Inform interested persons of their right to submit comments in writing to the Department relating to the proposed exemption and establish a deadline for receipt of such comments;

(d) If the proposed exemption includes relief from the prohibitions of section 406(b) of ERISA, section 4975(c)(1) (E) or (F) of the Code, or section 8477(c)(2) of FERSA, inform interested persons of their right to request a hearing under § 2570.46 of this part and establish a deadline for receipt of requests for such hearings.

§ 2570.43 Notification of interested persons by applicant.

(a) If, as set forth in the exemption application, the notification that an applicant intends to provide to interested persons upon publication of a notice of proposed exemption in the **Federal Register** is inadequate, the Department will so inform the applicant and will secure the applicant's written agreement to provide what it considers to be adequate notice under the circumstances.

(b) If a notice of proposed exemption is published in the **Federal Register** in accordance with § 2570.42 of this part, the applicant must notify interested persons of the pendency of the exemption in the manner and time period specified in the application or in any superseding agreement with the Department. Any such notification must include:

(1) A copy of the notice of proposed exemption; and

(2) A supplemental statement in the following form:

> You are hereby notified that the United States Department of Labor is considering granting an exemption from the prohibited transaction restrictions of the Employee Retirement Income Security Act of 1974, the Internal Revenue Code of 1986, or the Federal Employees' Retirement System Act of 1986. The exemption under consideration is explained in the enclosed Notice of Proposed Exemption. As a person who may be affected by this exemption, you have the right to comment on the proposed exemption by [date].[1] [If you may be adversely affected by the grant of the exemption, you also have the right to request a hearing on the exemption by [date].][2]
>
> Comments or requests for a hearing should be addressed to: Office of Exemption Determinations, Pension and Welfare Benefits Administration, room _____,[3] U.S. Department of Labor, 200 Constitution Avenue NW., Washington, DC 20210, ATTENTION: Application No. _____.[4]
>
> The Department will make no final decision on the proposed exemption until it reviews all comments received in response to the enclosed notice. If the Department decides to hold a hearing on the exemption before making its final decision, you will be notified of the time and place of the hearing.

(c) The method used to furnish notice to interested persons must be reasonably calculated to ensure that interested persons actually receive the notice. In all cases, personal delivery and delivery by first-class mail will be considered reasonable methods of furnishing notice.

(d) After furnishing the notice required by this section, an applicant must provide the Department with a statement confirming that notice was furnished to the persons and in the manner and time designated in its exemption application or in any

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[1] The applicant will write in this space the date of the last day of the time period specified in the notice of proposed exemption.

[2] To be added in the case of an exemption that provides relief from section 406(b) of ERISA or corresponding sections of the Code or FERSA.

[3] The applicant will fill in the room number of the Division of Exemptions. As of the date of this final regulation, the room number of the Division of Exemptions was N–5671.

[4] The applicant will fill in the exemption application number, which is stated in the notice of proposed exemption, as well as in all correspondence from the Department to the applicant regarding the application.

superseding agreement with the Department. This statement must be accompanied by a declaration under penalty of perjury attesting to the truth of the information provided in the statement and signed by a person qualified under § 2570.34(b)(5) of these procedures to sign such a declaration. No exemption will be granted until such a statement and its accompanying declaration have been furnished to the Department.

§ 2570.44 Withdrawal of exemption applications.

(a) An applicant may withdraw his application for an exemption at any time by informing the Department, either orally or in writing, of his intent to withdraw.

(b) Upon receiving an applicant's notice of intent to withdraw an application for an individual exemption, the Department will confirm by letter the applicant's withdrawal of the application and will terminate all proceedings relating to the application. If a notice of proposed exemption has been published in the **Federal Register**, the Department will publish a notice withdrawing the proposed exemption.

(c) Upon receiving an applicant's notice of intent to withdraw an application for a class exemption or for an individual exemption that is being considered with other applications as a request for a class exemption, the Department will inform any other applicants for the exemption of the withdrawal. The Department will continue to process other applications for the same exemption. If all applicants for a particular class exemption withdraw their applications, the Department may either terminate all proceedings relating to the exemption or propose the exemption on its own motion.

(d) If, following the withdrawal of an exemption application, an applicant decides to reapply for the same exemption, he may submit a letter to the Department requesting that the application be reinstated and referring to the application number assigned to the original application. If, at the time the original application was withdrawn, any additional information to be submitted to the Department under § 2570.39 of these procedures was outstanding, that information must accompany the letter requesting reinstatement of the application. However, the applicant need not resubmit information previously furnished to the Department in connection with a withdrawn application unless reinstatement of the application is requested more than two years after the date of its withdrawal.

(e) Any request for reinstatement of a withdrawn application submitted in accordance with paragraph (d) of this section, will be granted by the Department, and the Department will take whatever steps remained at the time the application was withdrawn to process the application.

§ 2570.45 Requests for reconsideration.

(a) The Department will entertain one request for reconsideration of an exemption application that has been finally denied pursuant to § 2570.41 (a)(2) or (a)(3) of this part if the applicant presents in support of the application significant new facts or arguments, which, for good reason, could not have been submitted for the Department's consideration during its initial review of the exemption application.

(b) A request for reconsideration of a previously denied application must be made within 180 days after the issuance of the final denial letter and must be accompanied by a copy of the Department's final letter denying the exemption and a statement setting forth the new information and/or arguments that provide the basis for reconsideration.

(c) A request for reconsideration must also be accompanied by a declaration under penalty of perjury attesting to the truth of the new information provided, which is signed by a person qualified under § 2570.34(b)(5) of these procedures to sign such a declaration.

(d) If, after reviewing a request for reconsideration, the Department decides that the facts and arguments presented do not warrant reversal of its original decision to deny the exemption, it will send a letter to the applicant reaffirming that decision.

(e) If, after reviewing a request for reconsideration, the Department decides, based on the new facts and arguments submitted, to reconsider its denial letter, it will notify the applicant of its intent to reconsider the application in light of the new information presented. The Department will then take whatever steps remained at the time it issued its final denial letter to process the exemption application.

(f) If, at any point during its subsequent processing of the application, the Department decides again that the exemption is unwarranted, it will issue a letter affirming its final denial.

§ 2570.46 Hearings in opposition to exemptions from restrictions on fiduciary self-dealing.

(a) Any interested person who may be adversely affected by an exemption which the Department proposes to grant from the restrictions of section 406(b) of ERISA, section 4975(c)(1)(E) or (F) of the Code, or section 8477(c)(2) of FERSA may request a hearing before the Department within the period of time specified in the **Federal Register** notice of the proposed exemption. Any such request must state:

(1) The name, address, and telephone number of the person making the request;

(2) The nature of the person's interest in the exemption and the manner in which the person would be adversely affected by the exemption; and

(3) A statement of the issues to be addressed and a general description of the evidence to be presented at the hearing.

(b) The Department will grant a request for a hearing made in accordance with paragraph (a) of this section where a hearing is necessary to fully explore material factual issues identified by the person requesting the hearing. However, the Department may decline to hold a hearing where:

(1) The request for the hearing does not meet the requirements of paragraph (a);

(2) The only issues identified for exploration at the hearing are matters of law; or

(3) The factual issues identified can be fully explored through the submission of evidence in written form.

(c) An applicant for an exemption must notify interested persons in the event that the Department schedules a hearing on the exemption. Such notification must be given in the form, time, and manner prescribed by the Department. Ordinarily, however, adequate notification can be given by providing to interested persons a copy of the notice of hearing published by the Department in the **Federal Register** within 10 days of its publication, using any of the methods approved in § 2570.43(c) of this part.

(d) After furnishing the notice required by paragraph (c) of this section, an applicant must submit a statement confirming that notice was given in the form, manner, and time prescribed. This statement must be accompanied by a declaration under penalty of perjury attesting to the truth of the information provided in the statement, which is signed by a person qualified under § 2570.34(b)(5) of these procedures to sign such a declaration.

§ 2570.47 Other hearings.

(a) In its discretion, the Department may schedule a hearing on its own motion where it determines that issues relevant to the exemption can be most fully or expeditiously explored at a hearing.

(b) An applicant for an exemption must notify interested persons of any hearing on an exemption scheduled by the Department in the manner described in § 2570.46(c). In addition, the applicant must submit a statement subscribed as true under penalty of perjury like that required in § 2570.46(d).

§ 2570.48 Decision to grant exemptions.

(a) If, after considering all the facts and representations submitted by an applicant in support of an exemption application, all the comments received in response to a notice of proposed exemption, and the record of any hearing held in connection with the proposed exemption, the Department determines that the exemption should be granted, it will publish a notice in the **Federal Register** granting the exemption.

(b) A **Federal Register** notice granting an exemption will summarize the transaction or transactions for which exemptive relief has been granted and will specify the conditions under which such exemptive relief is available.

§ 2570.49 Limits on the effect of exemptions.

(a) An exemption does not take effect or protect parties in interest from liability with respect to the exemption transaction unless the material facts and representations contained in the application and in any materials and documents submitted in support of the application were true and complete.

(b) An exemption is effective only for the period of time specified and only under the conditions set forth in the exemption.

(c) Only the specific parties to whom an exemption grants relief may rely on the exemption. If the notice granting an exemption does not limit exemptive relief to specific parties, all parties to the exemption transaction may rely on the exemption.

§ 2570.50 Revocation or modification of exemptions.

(a) If, after an exemption takes effect, changes in circumstances, including changes in law or policy, occur which call into question the continuing validity of the Department's original conclusions concerning the exemption, the Department may take steps to revoke or modify the exemption.

(b) Before revoking or modifying an exemption, the Department will publish a notice of its proposed action in the **Federal Register** and provide interested persons with an opportunity to comment on the proposed revocation or modification. In addition, the Department will give the applicant at least 30 days notice in writing of the proposed revocation or modification and the reasons therefor and will provide the applicant with the opportunity to comment on the revocation or modification.

(c) Ordinarily the revocation or modification of an exemption will have prospective effect only.

§ 2570.51 Public inspection and copies.

(a) The administrative record of each exemption application will be open to public inspection and copying at the Public Disclosure Branch, PWBA, U.S. Department of Labor, 200 Constitution Avenue, NW., Washington, DC 20210.

(b) Upon request, the staff of the Public Disclosure Branch will furnish photocopies of an administrative record, or any specified portion of that record, for a specified charge per page.

§ 2570.52 Effective Date.

This regulation is effective with respect to all applications for exemptions filed with the Department under section 408(a) of ERISA, section 4975(c)(2) of the Code, or 5 U.S.C. 8477(c)(3) at any time on or after September 10, 1990. Applications for exemptions under section 408(a) of ERISA and/or section 4975 of the Code filed before September 10, 1990, are governed by ERISA Procedure 75–1. Applications for exemption under 5 U.S.C. 8477(c)(3) filed before September 10, 1990, but after December 29, 1988 are governed by part 2585 of chapter XXV of title 29 of the *Code of Federal Regulations,* (section 29 CFR part 2585 as revised July 1, 1990). Applications under 5 U.S.C. 8477(c)(3) filed before December 29, 1988 are governed by ERISA Procedure 75–1.

PART 2585— [REMOVED]

3. The regulations in part 2585 of chapter XXV of title 29 of the Code of Federal Regulations are removed.

Signed at Washington, DC, this 27th day of July , 1990.

David G. Ball,

Assistant Secretary for Pension and Welfare Benefits, U.S. Department of Labor.

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